

EXHIBIT D

Marc Toggia, M.D.

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. : Master File No.
PELVIC REPAIR SYSTEM : 2:12-MD-
PRODUCTS LIABILITY LITIGATION : MDL 2327
 :
 : JOSEPH R.
THIS DOCUMENT RELATES TO : GOODWIN
THE CASES LISTED BELOW : US DISTRICT
 : JUDGE

Mullins, et al. v. Ethicon, Inc., et al.
2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.
2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.
2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.
2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.
2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.
2:13-cv-04517
Martinez v. Ethicon, Inc., et al.
2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.
2:13-cv-07283
Oxley v. Ethicon, Inc., et al.
2:13-cv-10150
Atkins, et al. v. Ethicon, Inc., et al.
2:13-cv-11022
Garcia v. Ethicon, Inc., et al.
2:13-cv-14355

(Caption Continued on Next Page)

- - -

October 2, 2015

VIDEOTAPED DEPOSITION MARC TOGLIA, M.D.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph| 917.591.5672 fax
deps@golkow.com

Marc Toggia, M.D.

Page 2	Page 4
<p>1 CAPTION CONTINUED:</p> <p>2</p> <p>3 Lowe v. Ethicon, Inc., et al.</p> <p>4 2:13-cv-14718</p> <p>5 Dameron, et al. v. Ethicon, Inc., et al.</p> <p>6 2:13-cv-14799</p> <p>7 Vanbuskirk, et al. v. Ethicon, Inc., et al.</p> <p>8 2:13-cv-16183</p> <p>9 Mullens, et al. v. Ethicon, Inc., et al.</p> <p>10 2:13-cv-16564</p> <p>11 Shears, et al. v. Ethicon, Inc., et al.</p> <p>12 2:13-cv-17012</p> <p>13 Javins, et al. v. Ethicon, Inc., et al.</p> <p>14 2:13-cv-18479</p> <p>15 Barr, et al. v. Ethicon, Inc., et al.</p> <p>16 2:13-cv-22606</p> <p>17 Lambert v. Ethicon, Inc., et al.</p> <p>18 2:13-cv-24393</p> <p>19 Cook v. Ethicon, Inc., et al.</p> <p>20 2:13-cv-29260</p> <p>21 Stevens v. Ethicon, Inc., et al.</p> <p>22 2:13-cv-29918</p> <p>23 Harmon v. Ethicon, Inc., et al.</p> <p>24 2:13-cv-31818</p> <p>25 Snodgrass v. Ethicon, Inc., et al.</p> <p>26 2:13-cv-31881</p> <p>27 Miller v. Ethicon, Inc., et al.</p> <p>28 2:13-cv-32627</p> <p>29 Matney, et al. v. Ethicon, Inc., et al.</p> <p>30 2:14-cv-09195</p> <p>31 Jones, et al. v. Ethicon, Inc., et al.</p> <p>32 2:14-cv-09517</p> <p>33 Humbert v. Ethicon, Inc., et al.</p> <p>34 2:14-cv-10640</p> <p>35 Gillum, et al. v. Ethicon, Inc., et al.</p> <p>36 2:14-cv-12756</p> <p>37 Whisner, et al. v. Ethicon, Inc., et al.</p> <p>38 2:14-cv-13023</p> <p>39 Tomblin v. Ethicon, Inc., et al.</p> <p>40 2:14-cv-14664</p> <p>41 Schepleng v. Ethicon, Inc., et al.</p> <p>42 2:14-cv-16061</p> <p>43 Tyler, et al. v. Ethicon, Inc., et al.</p> <p>44 2:14-cv-19110</p> <p>45 (Caption Continued on Next Page)</p>	<p>1 APPEARANCES:</p> <p>2</p> <p>3 MOTLEY RICE LLC</p> <p>4 BY: MARGARET M. THOMPSON, MD, JD, ESQUIRE</p> <p>5 BY: BREANNE V. COPE, ESQUIRE</p> <p>6 28 Bridgeside Boulevard</p> <p>7 Mount Pleasant, South Carolina 29464</p> <p>8 (843) 216-9000</p> <p>9 Mthompsonmd@gmail.com</p> <p>10 Bcope@motleyrice.com</p> <p>11 Representing the Plaintiffs</p> <p>12</p> <p>13 BUTLER SNOW, LLP</p> <p>14 BY: NILS B. (BURT) SNELL, ESQUIRE</p> <p>15 500 Office Center Drive</p> <p>16 Suite 400</p> <p>17 Fort Washington, Pennsylvania 19034</p> <p>18 (215) 513-1885</p> <p>19 Burt.snell@butlersnow.com</p> <p>20 Representing the Defendant</p> <p>21</p> <p>22 ALSO PRESENT: Gregory Fields, Videographer</p> <p>23</p> <p>24 - - -</p>
Page 3	Page 5
<p>1 CAPTION CONTINUED:</p> <p>2</p> <p>3 Kelly, et al. v. Ethicon, Inc., et al.</p> <p>4 2:14-cv-22079</p> <p>5 Lundell v. Ethicon, Inc., et al.</p> <p>6 2:14-cv-24911</p> <p>7 Cheshire, et al. v. Ethicon, Inc., et al.</p> <p>8 2:14-cv-24999</p> <p>9 Burgoyne, et al. v. Ethicon, Inc., et al.</p> <p>10 2:14-cv-28620</p> <p>11 Bennett, et al. v. Ethicon, Inc., et al.</p> <p>12 2:14-cv-29624</p> <p>13</p> <p>14 - - -</p> <p>15 OCTOBER 2, 2015</p> <p>16 - - -</p> <p>17</p> <p>18 Videotape deposition of</p> <p>19 MARC TOGLIA, M.D., taken pursuant to</p> <p>20 notice, was held at the law offices of</p> <p>21 Drinker Biddle and Reath, LLP, One Logan</p> <p>22 Square, 18th and Cherry Streets, Suite 2000,</p> <p>23 Philadelphia, Pennsylvania 19103,</p> <p>24 commencing at 1:26 p.m., on the above</p> <p>25 date, before Amanda Dee Maslinsky-Miller,</p> <p>26 a Certified Realtime Reporter and Notary</p> <p>27 Public in and for the State of</p> <p>28 Pennsylvania.</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p>	<p>1 - - -</p> <p>2 I N D E X</p> <p>3 - - -</p> <p>4</p> <p>5 Testimony of: MARC TOGLIA, M.D.</p> <p>6 By Ms. Thompson 10. 393</p> <p>7 By Mr. Snell 322</p> <p>8</p> <p>9 - - -</p> <p>10 E X H I B I T S</p> <p>11 - - -</p> <p>12 NO. DESCRIPTION PAGE</p> <p>13 Toglia-1 Notice of Videotaped</p> <p>14 Deposition Pursuant to</p> <p>15 Rule 30 and Document</p> <p>16 Requests Pursuant to</p> <p>17 Rule 34 of Marc</p> <p>18 Toglia, M.D. 20</p> <p>19 Toglia-2 Expert Report of</p> <p>20 Marc R. Toglia, M.D. 26</p> <p>21 Toglia-3 Invoices 27</p> <p>22 Toglia-4 3/19/09 E-mail from</p> <p>23 Marc Toglia to</p> <p>24 Kathleen Feeney;</p> <p>Subject: Re: These events</p> <p>Were approved 3.25</p> <p>Proctorship and 4.21</p> <p>Preceptorship 87</p>

2 (Pages 2 to 5)

Marc Toggia, M.D.

Page 6				Page 8			
1	- - -			1	- - -		
2	E X H I B I T S			2	DEPOSITION SUPPORT INDEX		
3	- - -			3	- - -		
4				4			
5	NO. DESCRIPTION PAGE			5	Direction to Witness Not to Answer		
6	Toggia-5 10/23/08 E-mail from			6	Page Line Page Line Page Line		
7	Kathleen Toggia to			7	17 22		
8	Cindy Pypcznski; Subject:			8			
9	FDA Toggia 99			9			
10	Toggia-6 4/27/09 E-mail from			10	Request for Production of Documents		
11	Marc Toggia to Kathleen			11	Page Line Page Line Page Line		
12	Feeney; Subject: RE:			12	53 4 110 17		
13	Itinerary for TVT			13	53 8		
14	Proctorship 108			14			
15	Toggia-7 Bates ETH.MESH 05225354			15	Stipulations		
16	05225380-384; TVT			16	Page Line Page Line Page Line8		
17	Instructions for Use 228			17	7 1		
18	Toggia-8 ETH.MESH 08696131-132			18			
19	Exhibit C - Clinical			19	Question Marked		
20	Trials 239			20	Page Line Page Line Page Line		
21	Toggia-9 ETH.MESH 02026591-595			21	None		
22	Material Safety Data Sheet 279			22			
23				23			
24				24			
Page 7				Page 9			
1	- - -			1	- - -		
2	E X H I B I T S			2	(It is hereby stipulated and		
3	- - -			3	agreed by and among counsel that		
4				4	sealing, filing and certification		
5	NO. DESCRIPTION PAGE			5	are waived; and that all		
6	Toggia-14 ETH.MESH 03617772			6	objections, except as to the form		
7	Consultant Invoice			7	of the question, will be reserved		
8	Dated 5/28/09 303			8	until the time of trial.)		
9				9	- - -		
10	Toggia-15 ETH.MESH 10399348			10	THE VIDEOGRAPHER: We are		
11	4/29/09 E-mail from			11	now on the record. My name is		
12	Patricia Beach to Judi			12	Gregory Fields. I'm a		
13	Gauld; Subject: FW:			13	videographer for Golkow		
14	PROSIMATM Registry 314			14	Technologies. Today's date is		
15				15	October 2nd, 2015, and the time is		
16	Toggia-16 ETH.MESH 11838868-869			16	1:26 p.m. This video deposition		
17	5/30/07 E-mail from			17	is being held in Philadelphia,		
18	Kathleen Feeney to Cindy			18	Pennsylvania, in the matter of In		
19	Pypcznski; Subject: FW:			19	Re: Ethicon, U.S. District Court,		
20	Surgery at Lankenau 320			20	Southern District of West		
21				21	Virginia. The deponent is Marc		
22	Toggia-17 Level of Evidence Chart 326			22	Toggia. Counsel will be noted on		
23				23	the stenographic record. The		
24				24	court reporter is Amanda Miller		
	Toggia-18 Level of Evidence Pyramid 327						
	Toggia-19 NICE Urinary Incontinence:						
	The Management of Urinary						
	Incontinence in Women 380						
	Toggia-20 Hernia Repair Surgery,						
	Volker Schumpelick,						
	Robert J. Fitzgibbons,						
	Editors 383						
	Toggia-21 The Cochrane Collaboration;						
	Mid-Urethral Sling						
	Operations for Stress Urinary						
	Incontinence in						
	Women (Review) 383						

3 (Pages 6 to 9)

Marc Toggia, M.D.

Page 10	Page 12
<p>1 and will now swear in the witness. 2 - - - 3 MARC TOGLIA, M.D., after 4 having been duly sworn, was 5 examined and testified as follows: 6 - - - 7 EXAMINATION 8 - - - 9 BY MS. THOMPSON: 10 Q. Dr. Toggia, I'm Margaret 11 Thompson, I represent the plaintiffs in 12 their case against Ethicon. 13 And you understood that -- 14 you understand that that's why you're 15 here today? 16 A. Yes, I do. 17 Q. Could you please state your 18 name for the record? 19 A. Yes. Marc Richard Toggia. 20 Q. And what is your occupation, 21 Dr. Toggia? 22 A. I'm a physician. 23 Q. Do you have a specialty? 24 A. Yes. I'm board certified in</p>	<p>1 Research. 2 Q. So am I understanding 3 correctly that you have a private 4 practice as well as your academic 5 appointment? 6 A. Yes. 7 Q. So you're paid by the 8 academic institutions and then you also 9 have -- receive income from your private 10 practice; is that correct? 11 A. There's no financial 12 compensation for the academic 13 appointments. 14 Q. For either -- 15 A. For the -- 16 Q. -- one of the academic 17 appointments? 18 Okay. So your income, then, 19 is derived strictly from your private 20 practice of urogynecology? 21 A. That is correct. 22 Q. And would you consider that 23 a specialty practice? 24 A. It's a subspecialty</p>
Page 11	Page 13
<p>1 female pelvic medicine and reconstructive 2 surgery. 3 Q. Are you also board certified 4 in OB/GYN? 5 A. That is correct. I'm double 6 board certified. 7 Q. What is your office address 8 currently? 9 A. It's 1098 West Baltimore 10 Pike, Media, Pennsylvania, Healthcare 11 Center 3, Suite 3404. 12 Q. And who is your employer? 13 A. I'm employed by Main Line 14 Healthcare. 15 Q. Do you have an academic 16 appointment as well? 17 A. I have several. I'm an 18 associate professor of obstetrics and 19 gynecology at what we formerly called 20 Thomas Jefferson School of Medicine, is 21 now the Sidney Kimmel School of Medicine. 22 And I'm also an associate 23 professor, clinical associate professor 24 at the Lankenau Institute of Medical</p>	<p>1 practice. 2 Q. A subspecialty practice. 3 So you are a referral 4 practice, so to speak? 5 A. Yes. I exclusively take 6 care of women that have urinary 7 incontinence and pelvic floor disorders. 8 Q. And are those patients 9 typically referred to you by other 10 physicians? 11 A. My patients may come from 12 sisters, mothers, former patients, other 13 physicians. The bulk of my practice 14 probably comes from other physicians. 15 Q. And do you do, as part of 16 that subspecialty practice, general GYN 17 as well or restrict it completely to 18 urogynecology? 19 A. I don't consider my practice 20 general gynecology. I mean, occasionally 21 a gynecologist may send me a patient for 22 an opinion that might have a general 23 gynecology, but that's not what I hold 24 myself out as.</p>

4 (Pages 10 to 13)

Marc Toggia, M.D.

<p style="text-align: right;">Page 14</p> <p>1 Q. So, typically, you would not</p> <p>2 be doing annual checkups, Pap smears,</p> <p>3 mammograms, birth control, that sort of</p> <p>4 thing that a general gynecologist might</p> <p>5 do?</p> <p>6 MR. SNELL: Hold on.</p> <p>7 Objection. Compound. Overbroad.</p> <p>8 Go ahead.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. And when you're treating a</p> <p>12 patient for a urogynecological condition,</p> <p>13 we'll get to what those are a little bit</p> <p>14 later, and that condition is resolved, do</p> <p>15 you then send that patient back to their</p> <p>16 general gynecologist or primary care</p> <p>17 physician?</p> <p>18 A. Yes.</p> <p>19 Q. And that would be because,</p> <p>20 one of the reasons, at least, is that</p> <p>21 physicians don't want to send their</p> <p>22 patients to a subspecialty and then lose</p> <p>23 their patients to their care; is that</p> <p>24 right?</p>	<p style="text-align: right;">Page 16</p> <p>1 hospital system is located in suburban</p> <p>2 Philadelphia; it consists of Lankenau</p> <p>3 Medical Center, Bryn Mawr Hospital, Paoli</p> <p>4 Hospital and Riddle Hospital.</p> <p>5 Q. And do you do surgeries at</p> <p>6 all four of those facilities as well?</p> <p>7 A. No.</p> <p>8 Q. Which ones do you perform</p> <p>9 surgeries at?</p> <p>10 A. I will operate at Riddle</p> <p>11 Hospital, Paoli Hospital and Lankenau</p> <p>12 Medical Center. My schedule does not</p> <p>13 allow me to operate at, say, Bryn Mawr</p> <p>14 Hospital. Although I have, from time to</p> <p>15 time, gone through; but I don't consider</p> <p>16 that to be a hospital that I would use</p> <p>17 for surgical procedures.</p> <p>18 Q. Do you have privileges or do</p> <p>19 surgery at any type of surgical center,</p> <p>20 freestanding surgical center?</p> <p>21 A. I do not.</p> <p>22 Q. So minor surgeries or those</p> <p>23 that would be output surgeries are done</p> <p>24 in the hospital as well?</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I don't know that I would</p> <p>2 agree with that statement. Let me</p> <p>3 clarify that. I take care of chronic</p> <p>4 disease.</p> <p>5 So it's not unusual for us</p> <p>6 to maintain a lifetime relationship with</p> <p>7 these patients. But if I understand you</p> <p>8 correctly, if I were to take care of a</p> <p>9 specific pelvic floor disorder and that</p> <p>10 person was to need, say, a mammogram, a</p> <p>11 Pap smear or some other kind of primary</p> <p>12 care service, we are not the ones</p> <p>13 primarily responsible for that, and they</p> <p>14 would go back to their referring doctor</p> <p>15 or the doctor of their choosing.</p> <p>16 Q. Understood. And what if the</p> <p>17 patient's pelvic floor disorder is cured,</p> <p>18 same thing?</p> <p>19 A. Yes.</p> <p>20 Q. What hospitals do you</p> <p>21 currently have privileges at?</p> <p>22 A. Currently, I'm privileged at</p> <p>23 all four of Main Line Healthcare</p> <p>24 hospitals. The Main Line Healthcare</p>	<p style="text-align: right;">Page 17</p> <p>1 A. I think, technically, the</p> <p>2 outpatient surgical surgeries are on</p> <p>3 hospital property, but I think that they</p> <p>4 are designated as -- you know, there's</p> <p>5 ambulatory surgery.</p> <p>6 Q. Are they on a different</p> <p>7 floor --</p> <p>8 A. No.</p> <p>9 Q. -- from the main operating</p> <p>10 room?</p> <p>11 A. It's all -- it's the same.</p> <p>12 I mean, patients are classified by their</p> <p>13 status not by physical location.</p> <p>14 Q. Okay. Are you married, Dr.</p> <p>15 Toggia?</p> <p>16 A. I am.</p> <p>17 Q. Children?</p> <p>18 A. Yes.</p> <p>19 Q. How many?</p> <p>20 A. I have two children.</p> <p>21 Q. What are their ages?</p> <p>22 MR. SNELL: Not relevant.</p> <p>23 Don't answer that question.</p> <p>24 MS. THOMPSON: You're</p>

5 (Pages 14 to 17)

Marc Toggia, M.D.

Page 18	Page 20
<p>1 instructing him not to answer?</p> <p>2 MR. SNELL: Yes. That's</p> <p>3 private. About his children? He</p> <p>4 came here to give opinions on the</p> <p>5 defect and the question that, that</p> <p>6 the judge posed about TVT, not to</p> <p>7 tell you about his children.</p> <p>8 MS. THOMPSON: I'm just</p> <p>9 getting to know him.</p> <p>10 MR. SNELL: No, that's not</p> <p>11 appropriate. I don't ask your</p> <p>12 experts about who their children</p> <p>13 are and their ages and stuff.</p> <p>14 That is totally inappropriate.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. You can go ahead and answer.</p> <p>17 MS. THOMPSON: Unless you're</p> <p>18 instructing him not to answer?</p> <p>19 MR. SNELL: Yes, I'm</p> <p>20 instructing him not to answer. I</p> <p>21 think that violates his privacy,</p> <p>22 is totally outside the scope, is</p> <p>23 not relevant.</p> <p>24 MS. THOMPSON: Okay. Object</p>	<p>1 be medical malpractice cases?</p> <p>2 A. Most of them are medical</p> <p>3 malpractice cases.</p> <p>4 My reason for pausing, I</p> <p>5 think one actually involved a piercing or</p> <p>6 tattoo parlor that was involved. And I</p> <p>7 don't think that's medical malpractice,</p> <p>8 but there were medical claims.</p> <p>9 Q. And did you testify for the</p> <p>10 defense or the plaintiffs or a mix in</p> <p>11 those cases?</p> <p>12 A. I've done a mix.</p> <p>13 Q. Did any of those cases that</p> <p>14 you have given depositions in relate to</p> <p>15 mesh products?</p> <p>16 A. To the best of my knowledge,</p> <p>17 no.</p> <p>18 Q. Dr. Toggia, did you --</p> <p>19 - - -</p> <p>20 (Whereupon, Exhibit</p> <p>21 Toggia-1, Notice of Videotaped</p> <p>22 Deposition Pursuant to Rule 30 and</p> <p>23 Document Requests Pursuant to Rule</p> <p>24 34 of Marc Toggia, M.D., was</p>
Page 19	Page 21
<p>1 to form is sufficient.</p> <p>2 THE WITNESS: Thank you. I</p> <p>3 appreciate that. And I agree.</p> <p>4 BY MS. THOMPSON:</p> <p>5 Q. Have you given previous</p> <p>6 depositions?</p> <p>7 A. Yes.</p> <p>8 Q. How many?</p> <p>9 A. I honestly couldn't tell you</p> <p>10 off the top of my head. Probably no more</p> <p>11 than a dozen. I don't think I've given a</p> <p>12 deposition in over ten years, to the best</p> <p>13 of my -- my knowledge.</p> <p>14 Q. So somewhere in the range of</p> <p>15 five to twelve, would you ballpark it?</p> <p>16 A. Yes.</p> <p>17 Q. And what types of cases were</p> <p>18 those depositions given in?</p> <p>19 A. The vast majority of them,</p> <p>20 if not all of them, were within the realm</p> <p>21 of female pelvic floor disorders, areas</p> <p>22 of my expertise, which oftentimes extends</p> <p>23 into the obstetrical world.</p> <p>24 Q. So am I correct those would</p>	<p>1 marked for identification.)</p> <p>2 - - -</p> <p>3 MS. THOMPSON: We've marked</p> <p>4 as Exhibit-1 the notice for your</p> <p>5 deposition today.</p> <p>6 MR. SNELL: Thank you.</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. Have you had a chance to --</p> <p>9 MR. SNELL: Let me -- I just</p> <p>10 want to give him the original,</p> <p>11 that way the ones don't get mixed</p> <p>12 up.</p> <p>13 MS. THOMPSON: Sure. Thank</p> <p>14 you.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Have you had a chance to see</p> <p>17 this document prior to just now?</p> <p>18 A. I have.</p> <p>19 Q. When did you first see this?</p> <p>20 A. I was given this document,</p> <p>21 probably, near the end of last week, to</p> <p>22 the best of my knowledge.</p> <p>23 Q. And did you see Schedule A,</p> <p>24 which is attached to the notice of</p>

6 (Pages 18 to 21)

Marc Toggia, M.D.

Page 22	Page 24
<p>1 deposition?</p> <p>2 A. Yes.</p> <p>3 Q. And it asked you to bring,</p> <p>4 oh, a whole bunch of documents. And I'm</p> <p>5 not going to go through these</p> <p>6 individually.</p> <p>7 But can you just tell me</p> <p>8 what you brought with you today?</p> <p>9 A. Yes. To the best of my</p> <p>10 knowledge, I have brought, as you put it,</p> <p>11 as a whole bunch of documents, as they</p> <p>12 relate to Schedule A.</p> <p>13 Q. And those are contained in</p> <p>14 the -- some boxes that you brought to the</p> <p>15 conference room?</p> <p>16 A. Yes. Some are electronic,</p> <p>17 the majority of them are copied on paper.</p> <p>18 Q. And I think Mr. Snell</p> <p>19 provided me a flash drive with everything</p> <p>20 that's in the boxes, correct?</p> <p>21 MR. SNELL: As far as I</p> <p>22 know. Although, he's brought</p> <p>23 thumb drives, too.</p> <p>24 MS. THOMPSON: Okay.</p>	<p>1 best of my knowledge, I have done my best</p> <p>2 to comply and everything is -- is as it</p> <p>3 is listed.</p> <p>4 MR. SNELL: I will make one</p> <p>5 note, just for a clean record,</p> <p>6 too, as he did say, since the time</p> <p>7 he published his report and his</p> <p>8 reliance materials list, there</p> <p>9 have been depositions of your</p> <p>10 experts. He, obviously, has those</p> <p>11 and I think he might have even</p> <p>12 said that.</p> <p>13 But when she asks you a</p> <p>14 question you are allowed to take</p> <p>15 them and look at them and tell her</p> <p>16 what you reviewed.</p> <p>17 THE WITNESS: Understood.</p> <p>18 MS. THOMPSON: And we'll</p> <p>19 maybe take a brief look at it at</p> <p>20 the break.</p> <p>21 MR. SNELL: That's fine. He</p> <p>22 brought it here, it's up to you.</p> <p>23 You can look at it, copy it, do</p> <p>24 whatever you want.</p>
Page 23	Page 25
<p>1 MR. SNELL: So, I mean --</p> <p>2 and also, I mean, you may want to</p> <p>3 ask him, but he's done his own</p> <p>4 research. So he may have stuff</p> <p>5 that I don't even have.</p> <p>6 MS. THOMPSON: I think I</p> <p>7 should do that.</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. Dr. Toggia, could you just</p> <p>10 go through what you brought here and</p> <p>11 describe what you have? Not document by</p> <p>12 document, but generally speaking.</p> <p>13 A. Generally speaking, I have</p> <p>14 brought the relevant clinical studies and</p> <p>15 other published research, as well as the</p> <p>16 legal documents, including the expert</p> <p>17 reports and depositions.</p> <p>18 Q. Did you bring anything with</p> <p>19 you that is not included on your -- the</p> <p>20 reliance list that's attached to your</p> <p>21 report?</p> <p>22 A. Obviously, I can't claim to</p> <p>23 have an independent knowledge of every</p> <p>24 specific element on that list, but to the</p>	<p>1 MS. THOMPSON: I appreciate</p> <p>2 that.</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Did you bring any billing</p> <p>5 records with you today?</p> <p>6 MR. SNELL: I have those. I</p> <p>7 have them somewhere.</p> <p>8 Let's go off the record for</p> <p>9 a second.</p> <p>10 VIDEO TECHNICIAN: We are</p> <p>11 off the record. The time is 1:38</p> <p>12 p.m.</p> <p>13 - - -</p> <p>14 (Whereupon, a discussion off</p> <p>15 the record occurred.)</p> <p>16 - - -</p> <p>17 VIDEO TECHNICIAN: We are</p> <p>18 back on the video record.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Dr. Toggia, I think you</p> <p>21 brought your report that you prepared in</p> <p>22 this case --</p> <p>23 A. Yes.</p> <p>24 Q. -- is that correct?</p>

7 (Pages 22 to 25)

Marc Toggia, M.D.

Page 26	Page 28
<p>1 - - -</p> <p>2 (Whereupon, Exhibit</p> <p>3 Toggia-2, Expert Report of Marc R.</p> <p>4 Toggia, M.D., was marked for</p> <p>5 identification.)</p> <p>6 - - -</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. And we have marked that as</p> <p>9 Exhibit Number 2.</p> <p>10 I believe you have your own</p> <p>11 copy as well?</p> <p>12 A. I do.</p> <p>13 Q. Do you have any notes on</p> <p>14 your copy that you brought with you?</p> <p>15 A. I mean, I've got some</p> <p>16 underlines in pencil. I may have made a</p> <p>17 spelling correction. I don't have any</p> <p>18 prose of any kind in there.</p> <p>19 Q. There's a curriculum vitae</p> <p>20 attached to that report --</p> <p>21 A. Yes.</p> <p>22 Q. -- as you recall.</p> <p>23 Is that a current C.V.?</p> <p>24 A. It is.</p>	<p>1 hours you have worked on this case since</p> <p>2 September 24th? That would be in the</p> <p>3 last week or so.</p> <p>4 A. Would it be sufficient if I</p> <p>5 told you that I've probably done -- used</p> <p>6 a total of about 50 hours in total?</p> <p>7 Q. So 50 hours total on this</p> <p>8 case to date?</p> <p>9 A. 50 hours --</p> <p>10 Q. Approximately?</p> <p>11 A. Approximately 50 hours of</p> <p>12 work on this case.</p> <p>13 Q. How many hours did you spend</p> <p>14 preparing your report, approximately?</p> <p>15 A. Approximately 23 years and</p> <p>16 50 hours.</p> <p>17 And the reason why I say</p> <p>18 that, counselor, is that most of the</p> <p>19 material that I have reviewed, I have</p> <p>20 reviewed over the span of my career. And</p> <p>21 that would include, perhaps, reviewing it</p> <p>22 prior to being published, watching it be</p> <p>23 presented at meetings, having read it</p> <p>24 over and over for my own personal, you</p>
Page 27	Page 29
<p>1 Q. Are there any additions that</p> <p>2 you would make to that, sitting here</p> <p>3 today --</p> <p>4 A. No.</p> <p>5 Q. -- that you can think of?</p> <p>6 MS. THOMPSON: So Exhibit-2</p> <p>7 will be the report and the -- with</p> <p>8 the C.V.</p> <p>9 - - -</p> <p>10 (Whereupon, Exhibit</p> <p>11 Toggia-3, Invoices, was marked for</p> <p>12 identification.)</p> <p>13 - - -</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. And it looks like you also</p> <p>16 brought, today, two bills or invoices for</p> <p>17 your work in this case, and we've marked</p> <p>18 that as Exhibit Number 3.</p> <p>19 A. Thank you.</p> <p>20 Q. Do those look familiar?</p> <p>21 A. Yes.</p> <p>22 Q. And the last date on the</p> <p>23 invoice is September 24th.</p> <p>24 Can you approximate how many</p>	<p>1 know, knowledge and interest.</p> <p>2 And, certainly, many of</p> <p>3 these articles relate to the subspecialty</p> <p>4 board certification.</p> <p>5 Q. But you haven't billed</p> <p>6 Ethicon for 23 years, correct?</p> <p>7 A. I've told you that I've</p> <p>8 billed them for 50 hours, counselor,</p> <p>9 right. In formulating my opinion.</p> <p>10 Q. I'm just trying to break --</p> <p>11 break it down a little bit --</p> <p>12 A. Sure.</p> <p>13 Q. -- and try to understand how</p> <p>14 much of that 50 hours was actually</p> <p>15 preparing your report.</p> <p>16 And if you can't -- if</p> <p>17 you're not -- unable to do that, that's</p> <p>18 fine.</p> <p>19 A. In preparing the report, it</p> <p>20 probably is, both of these, 10 hours plus</p> <p>21 33 hours, 43 hours; and the difference is</p> <p>22 probably split between preparing for the</p> <p>23 deposition and additional work finalizing</p> <p>24 the report.</p>

8 (Pages 26 to 29)

Marc Toggia, M.D.

Page 30	Page 32
<p>1 Q. So that would include review 2 of literature, for instance? 3 A. Correct. 4 Q. When were you first 5 contacted to serve as an expert in this 6 case? 7 A. If memory serves me right, 8 it was some time in August. 9 Q. And do you have any 10 correspondence regarding that initial 11 contact? 12 A. I do not. 13 Q. Was it a phone call? 14 A. Correct. 15 Q. From Mr. Snell or another 16 attorney? 17 A. From Mr. Snell. 18 Q. And what did Mr. Snell ask 19 you to do? 20 A. Mr. Snell apprised me to the 21 existence of the case and that he needed 22 to retain an expert to specifically 23 comment on the claims as they relate to 24 the safety, the design of the TVT</p>	<p>1 MR. SNELL: I will say that 2 I -- I provided this list. 3 MS. THOMPSON: Fair enough. 4 BY MS. THOMPSON: 5 Q. And these were the articles 6 that Mr. Snell provided you with as well? 7 A. Yes. 8 MR. SNELL: I will make one 9 note for the record. He sent 10 articles and things to me that I 11 told paralegals to put on this 12 list, okay? 13 MS. THOMPSON: Fair enough. 14 MR. SNELL: So I tried to 15 capture whatever he went out and 16 found, just so you would have it. 17 BY MS. THOMPSON: 18 Q. So the list would include 19 articles that Mr. Snell provided you, 20 articles that you thought were relevant 21 that you sent back to him, and those were 22 just -- 23 A. Right. And to be clear, 24 there was a large degree of duplication</p>
Page 31	Page 33
<p>1 product. 2 Q. Did he provide you with 3 materials to review? 4 A. Mr. Snell provided me with, 5 I believe, the original complaint and, of 6 course, my access to the internal 7 documents from the company and from the 8 plaintiffs' experts and the exhibits. 9 Q. Did he also provide you with 10 literature? 11 A. Yes. 12 Q. And so on your reliance list 13 that's attached to your report, does that 14 include the literature that Mr. Snell 15 provided you? 16 A. To be completely honest with 17 you, there was very little on that list 18 that I was not already familiar with. 19 Q. So you were familiar with 20 the majority of the articles on the list. 21 But the list was provided by 22 counsel; is that correct? 23 MR. SNELL: Correct, yes. 24 THE WITNESS: Yes.</p>	<p>1 between things that I had already had in 2 my possession and things that were on his 3 list. 4 Q. And I actually noticed that 5 there were some duplications on the list 6 itself, because of minor variations in 7 the citation or whatever. 8 And, I guess, that might 9 have been the case on some of those, 10 correct? 11 A. Counselor, I'm sorry, I'm 12 not -- I'm not familiar with what, 13 specifically, you're referring to or what 14 you're -- 15 Q. Okay. Are all the opinions 16 that you intend to provide at trial 17 contained in this report? 18 A. Yes. With the exception of 19 anything that I might discover, you know, 20 between now and then that might be of 21 relevance. 22 Q. Okay. And you mentioned 23 depositions that you reviewed. And some 24 of those are listed on the reliance list,</p>

9 (Pages 30 to 33)

Marc Toggia, M.D.

Page 34	Page 36
<p>1 if you look on the last page.</p> <p>2 Are there any that come to</p> <p>3 mind that you've reviewed in addition to</p> <p>4 these?</p> <p>5 A. I'm not sure that I have</p> <p>6 what you're referring to as a reliance</p> <p>7 page.</p> <p>8 Q. Attached to your report.</p> <p>9 A. Oh, I'm sorry.</p> <p>10 Yes, I would say the ones</p> <p>11 that come to mind would be the</p> <p>12 deposition -- the recent depositions of</p> <p>13 the plaintiffs' experts, which would</p> <p>14 include Dr. Blaivas, Dr. Rosenzweig and</p> <p>15 Dr. Elliott.</p> <p>16 Q. So the depositions of Drs.</p> <p>17 Blaivas, Rosenzweig and Elliott are in</p> <p>18 addition to the reports listed here?</p> <p>19 A. Correct.</p> <p>20 MR. SNELL: I'll make a</p> <p>21 note, for the record, that he may</p> <p>22 have opinions regarding those</p> <p>23 expert depositions.</p> <p>24 BY MS. THOMPSON:</p>	<p>1 perhaps, I explain to you my</p> <p>2 methodology, as far as what --</p> <p>3 what I did in terms of formulating</p> <p>4 the opinion and what I found, what</p> <p>5 I -- what I was told was sort of</p> <p>6 my charge, so to speak?</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. Sure.</p> <p>9 A. I think that will just make</p> <p>10 what I'm about to say more -- sort of</p> <p>11 more relevant.</p> <p>12 So it was my understanding</p> <p>13 that I was to formulate an opinion</p> <p>14 whether or not the design of the TVT was</p> <p>15 reasonably safe for its intended use for</p> <p>16 the treatment of stress incontinence in</p> <p>17 women versus whether or not it was</p> <p>18 defective in its design.</p> <p>19 In formulating my opinion, I</p> <p>20 looked at the high-quality studies. By</p> <p>21 that I mean those that we would consider</p> <p>22 to be Level 1 evidence, things such as</p> <p>23 randomized control trials, systematic</p> <p>24 reviews, the prospective longitudinal</p>
Page 35	Page 37
<p>1 Q. Do you have any opinions</p> <p>2 related to the expert depositions that</p> <p>3 you reviewed that you can relate to me at</p> <p>4 this time?</p> <p>5 A. I do.</p> <p>6 Q. Why don't you go ahead --</p> <p>7 that are different from what you have in</p> <p>8 your report?</p> <p>9 A. I don't know that I would</p> <p>10 say different. They would be, maybe,</p> <p>11 perhaps, in addition. That I might have</p> <p>12 opinions in addition to what I may have</p> <p>13 expressed in the report, if that makes</p> <p>14 sense to you.</p> <p>15 Q. Sure. Why don't you go</p> <p>16 ahead and, to the best of your ability,</p> <p>17 give me those additional opinions now?</p> <p>18 A. Where would you like me to</p> <p>19 start?</p> <p>20 Q. Wherever you want to start.</p> <p>21 MR. SNELL: You can -- do</p> <p>22 you want the depositions?</p> <p>23 THE WITNESS: Would it be</p> <p>24 helpful for you, counselor, if,</p>	<p>1 registry trials. All of these would</p> <p>2 constitute what we would consider to be</p> <p>3 Level 1 scientific evidence.</p> <p>4 From there, I reviewed the</p> <p>5 published position statements from the</p> <p>6 relevant specialty societies. And those</p> <p>7 would be sort of the high-quality data</p> <p>8 that I used to formulate my opinion.</p> <p>9 There were additional pieces</p> <p>10 of works, such as those exhibits -- I</p> <p>11 don't always know the legal term for</p> <p>12 these things -- that were provided by</p> <p>13 your experts, by the plaintiffs' experts</p> <p>14 that, of course, I would have looked at</p> <p>15 and considered, because, obviously, they</p> <p>16 were relevant in that regard.</p> <p>17 I will tell you, just to be</p> <p>18 clear, that, in general, things like</p> <p>19 bench research, in vitro studies, case</p> <p>20 series, we consider those to be Level</p> <p>21 5 -- expert opinion, Level 5 studies.</p> <p>22 And those, typically, are not very</p> <p>23 relevant or scientifically meaningful,</p> <p>24 especially when Level 1 evidence exists.</p>

10 (Pages 34 to 37)

Marc Toggia, M.D.

<p style="text-align: right;">Page 38</p> <p>1 And so those things, because 2 of their severe limitations, you can 3 never derive clinical inference or 4 medical conclusions, because the evidence 5 is so weak. 6 So while I am familiar and 7 have reviewed those studies and 8 documentations, typically, they don't 9 factor into the formulation of an 10 opinion. 11 In that regard, I would say, 12 as a general statement, I was struck by 13 the fact that all three of the expert 14 reports that I reviewed, and I'm 15 specifically referring to those by Dr. 16 Rosenzweig, Blaivas and Elliott, that 17 they were significantly devoid of similar 18 high-quality Level 1 evidence studies and 19 seemed to spend the majority of their 20 time looking at far less clinically 21 relevant Level 5 studies, such as animal 22 studies, bench research, in vitro 23 studies, unpublished observations, as 24 well as personal experience and expert</p>	<p style="text-align: right;">Page 40</p> <p>1 than happy to discuss those with you. 2 Q. All right. So it sounds 3 like the additional opinion that you're 4 giving are that the plaintiff experts' 5 reports are devoid of high-quality 6 studies? 7 MR. SNELL: Objection. He 8 told you a lot more than that. 9 THE WITNESS: Yes. I don't 10 think -- 11 BY MS. THOMPSON: 12 Q. I think that's -- 13 A. -- I can simplify it into a 14 single sentence. 15 Q. Now, you'll agree with me 16 that a position statement is not a 17 scientific study, correct? 18 A. A scientific -- I would not 19 agree with that statement. And let me 20 clarify. 21 A position statement is a 22 summary statement typically based upon a 23 systematic review or independent analysis 24 of Level 1 data.</p>
<p style="text-align: right;">Page 39</p> <p>1 opinion. 2 So as a general statement, 3 my additional opinion is that, you know, 4 the majority of what I've read from these 5 individuals is not of very high 6 scientific quality. 7 And I think that they have, 8 if I can be completely honest, 9 misrepresented data from levels of 10 evidence that do not allow you to make 11 clinical inference or draw conclusions 12 specifically as it would relate to the 13 design and safety of the TVT device and 14 specifically to its intended use for the 15 treatment of female stress incontinence. 16 Q. Let's go ahead and get to 17 the additional opinions that you have, 18 with that background. 19 A. Yes. 20 Q. What are those additional 21 opinions? 22 A. I think I've given you 23 what -- what those opinions are. I mean, 24 if you have specific questions, I'm more</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. But it's not a scientific 2 piece of literature? It's not peer 3 reviewed, is it? 4 MR. SNELL: Objection. 5 Asked and answered. 6 THE WITNESS: I disagree. 7 They -- they are peer reviewed. 8 All position statements are 9 formulated and then reviewed prior 10 to publication. In fact, the 11 majority of them, for example, 12 you'll see, are published in 13 peer-reviewed journals. You 14 cannot be published in a 15 peer-reviewed journal unless you 16 are peer reviewed. 17 BY MS. THOMPSON: 18 Q. Okay. Well, let's just 19 consider the AUGS position statement on 20 midurethral slings. 21 You're familiar with that 22 document, correct? 23 A. Yes. I have that document 24 here in my possession.</p>

11 (Pages 38 to 41)

Marc Toggia, M.D.

<p style="text-align: right;">Page 42</p> <p>1 Q. Do you know why that was 2 prepared? 3 A. Do I know why? Can you -- 4 I'm not sure if I understand what 5 you're -- what you're meaning. 6 Q. What was the purpose for the 7 preparation of that position statement by 8 AUGS? 9 A. The AUGS position statement 10 was -- was created to, as I stated, to 11 provide a summary statement based upon 12 high-quality scientific evidence in light 13 of -- I'm sorry for putting this, 14 unfounded claims regarding the design 15 defects and similar type statements. 16 Q. So if I told you that the 17 purpose, the reason that the AUGS 18 position statement was written was to use 19 in courtrooms, in litigation, would you 20 have any reason to doubt that? 21 A. Yes. 22 MR. SNELL: Hold on. Let 23 me -- let me -- you have to give 24 me a chance to object.</p>	<p style="text-align: right;">Page 44</p> <p>1 MR. SNELL: Hold on. Let 2 me -- you have to give me -- these 3 are totally without -- objection. 4 Lacks foundation. Misstates 5 evidence. 6 Go ahead. 7 THE WITNESS: I would not 8 believe what you're saying. Or I 9 don't believe what you're saying. 10 BY MS. THOMPSON: 11 Q. Is there anywhere in that 12 two-page position statement that mentions 13 complications or risks associated with 14 midurethral slings? 15 A. May I refer to it? 16 MR. SNELL: Of course. 17 MS. THOMPSON: Sure. 18 MR. SNELL: You can always 19 get it out. 20 That goes for any document 21 she asks you about. 22 THE WITNESS: Of course, it 23 has to be the one that's all the 24 way at the back.</p>
<p style="text-align: right;">Page 43</p> <p>1 THE WITNESS: Sorry. 2 MR. SNELL: Objection. 3 Lacks foundation. 4 Go ahead. 5 THE WITNESS: That 6 absolutely was not the reason. 7 BY MS. THOMPSON: 8 Q. And you're confident of 9 that? 10 A. I am confident of that, yes. 11 Q. Okay. And are you familiar 12 with the authors of that position 13 statement? 14 A. Yes. 15 Q. Are you familiar with the 16 authors' industry ties? 17 A. I can't tell you that I know 18 in any great detail what their ties are. 19 Q. If I told you that they all 20 have conflicts of interest regarding 21 their financial relationship with 22 industry, would you have any reason to 23 doubt that? 24 A. Yes.</p>	<p style="text-align: right;">Page 45</p> <p>1 MR. SNELL: Just so I'm 2 clear on the record, which one are 3 you talking about? 4 MS. THOMPSON: The AUGS 5 position statement on midurethral 6 slings. 7 MR. SNELL: There's a 8 couple. 9 THE WITNESS: There's one. 10 There's -- 11 MS. THOMPSON: I'm only 12 familiar with one position 13 statement. 14 - - - 15 (Whereupon, a discussion off 16 the record occurred.) 17 - - - 18 THE WITNESS: Counselor, 19 thank you for waiting. 20 I have in front of me the 21 AUGS/SUFU position statement on 22 mesh midurethral slings. I would 23 ask that you repeat the question 24 to me, please.</p>

12 (Pages 42 to 45)

Marc Toggia, M.D.

<p style="text-align: right;">Page 46</p> <p>1 BY MS. THOMPSON:</p> <p>2 Q. The question is, in this,</p> <p>3 actually, three-page position statement,</p> <p>4 is there any mention of complications or</p> <p>5 risks associated with midurethral slings?</p> <p>6 A. I believe that the purpose</p> <p>7 of the position statement was to</p> <p>8 acknowledge the fact that the midurethral</p> <p>9 sling was recognized as the worldwide</p> <p>10 standard of care and that the procedure</p> <p>11 was felt to be safe and effective.</p> <p>12 I don't believe that this</p> <p>13 was a document that was intended to</p> <p>14 address the question that you're asking</p> <p>15 me.</p> <p>16 Q. So the answer is no?</p> <p>17 MR. SNELL: Objection.</p> <p>18 Misstates.</p> <p>19 MS. THOMPSON: Well, it's a</p> <p>20 yes-or-no question.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Is there any mention of</p> <p>23 complications or risks in this three-page</p> <p>24 document?</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. I said -- there's a</p> <p>2 discussion of safety. That, to me, is</p> <p>3 not a discussion of safety.</p> <p>4 MR. SNELL: Objection. That</p> <p>5 is not a question. Move to strike</p> <p>6 the attorney comment.</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. Are there any complications</p> <p>9 of midurethral slings discussed in this</p> <p>10 position paper?</p> <p>11 A. Again, that was not the</p> <p>12 purpose of the paper. So I am not</p> <p>13 surprised that there would not be a</p> <p>14 specific discussion of that in that</p> <p>15 particular paper.</p> <p>16 But, again, that was one of</p> <p>17 a series of papers that AUGS published on</p> <p>18 that.</p> <p>19 Q. So your position is that the</p> <p>20 purpose of this position statement by</p> <p>21 AUGS and SUFU was to report on the</p> <p>22 clinical studies related to midurethral</p> <p>23 slings, but it was not necessary to</p> <p>24 comment on any complications or risks</p>
<p style="text-align: right;">Page 47</p> <p>1 MR. SNELL: He just told you</p> <p>2 it discussed the safety.</p> <p>3 MS. THOMPSON: He said --</p> <p>4 okay.</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. Let's -- show me where it</p> <p>7 discusses the safety.</p> <p>8 A. Counselor, on Page 2, under</p> <p>9 Number 4, The FDA has clearly stated that</p> <p>10 polypropylene midurethral sling is safe</p> <p>11 and effective in the treatment of stress</p> <p>12 urinary incontinence.</p> <p>13 In this document it is</p> <p>14 explicitly stated, That the FDA -- and</p> <p>15 I'll just paraphrase, The safety and</p> <p>16 effectiveness of multi-incision slings is</p> <p>17 well established in clinical trials.</p> <p>18 Q. It still doesn't -- it says</p> <p>19 it's safe.</p> <p>20 Does it discuss</p> <p>21 complications?</p> <p>22 A. Counselor, the question that</p> <p>23 you asked me is whether or not it was</p> <p>24 safe. I answered the question.</p>	<p style="text-align: right;">Page 49</p> <p>1 associated; is that your testimony?</p> <p>2 MR. SNELL: Objection.</p> <p>3 THE WITNESS: That's</p> <p>4 not what I --</p> <p>5 MR. SNELL: Hold on.</p> <p>6 Objection. Misstates testimony.</p> <p>7 MS. THOMPSON: I'm asking if</p> <p>8 that's his testimony. If it's</p> <p>9 not, he can tell me it's not.</p> <p>10 THE WITNESS: It is not my</p> <p>11 testimony, counselor.</p> <p>12 Again, to be clear, a</p> <p>13 position statement is exactly</p> <p>14 that, it's a statement on a</p> <p>15 position. And the position taken</p> <p>16 here was specifically and simply,</p> <p>17 midurethral slings are recognized</p> <p>18 as the worldwide standard of care</p> <p>19 for the treatment of stress</p> <p>20 urinary incontinence.</p> <p>21 The statement is that the</p> <p>22 procedure is safe, effective and</p> <p>23 has improved the quality of life</p> <p>24 for millions of women.</p>

13 (Pages 46 to 49)

Marc Toggia, M.D.

Page 50	Page 52
<p>1 BY MS. THOMPSON:</p> <p>2 Q. So, then, a position</p> <p>3 statement is an opinion, correct?</p> <p>4 A. A position statement is an</p> <p>5 opinion.</p> <p>6 Q. And I don't think we ever</p> <p>7 answered my question if there were any</p> <p>8 complications discussed, but I'd like for</p> <p>9 you to answer that yes or no.</p> <p>10 Were -- are any</p> <p>11 complications discussed in the position</p> <p>12 statement?</p> <p>13 MR. SNELL: Objection.</p> <p>14 Asked and answered.</p> <p>15 MS. THOMPSON: He has not</p> <p>16 answered it.</p> <p>17 THE WITNESS: That wasn't</p> <p>18 the purpose of the -- of the</p> <p>19 position statement.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. I didn't ask about the</p> <p>22 purpose.</p> <p>23 I asked you, are</p> <p>24 complications or risks discussed in this</p>	<p>1 reason I was confused, you didn't -- you</p> <p>2 didn't say that I used.</p> <p>3 You want -- are you -- are</p> <p>4 you asking about any presentation that is</p> <p>5 about pelvic mesh or are you specifically</p> <p>6 saying presentations that I contributed</p> <p>7 or I presented?</p> <p>8 Q. Given or contributed to by</p> <p>9 you.</p> <p>10 A. And the question was, I'm</p> <p>11 sorry, did I bring?</p> <p>12 Q. Did you bring any of those</p> <p>13 documents relating to presentations or</p> <p>14 lectures given or contributed to by you?</p> <p>15 A. I don't -- I don't -- I</p> <p>16 don't recall that I have those in my -- I</p> <p>17 don't have an independent recollection of</p> <p>18 those being in my possession.</p> <p>19 Q. Do you have PowerPoints</p> <p>20 relating to stress incontinence or mesh</p> <p>21 products?</p> <p>22 A. In general or with me?</p> <p>23 Q. In general first.</p> <p>24 A. Yes. I have PowerPoint -- I</p>
Page 51	Page 53
<p>1 position statement?</p> <p>2 A. They are not discussed in</p> <p>3 the position statement.</p> <p>4 Q. Thank you.</p> <p>5 Let's go back to the</p> <p>6 Schedule A on the notice of deposition.</p> <p>7 I want to ask you just about a handful of</p> <p>8 items to see if you brought them or had</p> <p>9 them in your possession.</p> <p>10 Number 13, do you -- did you</p> <p>11 bring any Ethicon products in your</p> <p>12 possession?</p> <p>13 A. I have no Ethicon products</p> <p>14 in my possession.</p> <p>15 Q. The documents or</p> <p>16 communications relating to presentations</p> <p>17 or lectures given to you concerning</p> <p>18 pelvic mesh, pelvic organ prolapse or</p> <p>19 stress urinary incontinence, did you</p> <p>20 bring those items with you?</p> <p>21 A. I'm sorry, I'm not -- I'm</p> <p>22 not --</p> <p>23 Q. Number 16. Sorry.</p> <p>24 A. Okay. I'm sorry. The</p>	<p>1 have given PowerPoint presentations in</p> <p>2 the past. I do not have any with me.</p> <p>3 Q. Could you get those for us</p> <p>4 and provide those to Mr. Snell?</p> <p>5 A. I don't -- I don't know that</p> <p>6 I have all presentations that I've ever</p> <p>7 given.</p> <p>8 Q. Could you provide to Mr.</p> <p>9 Snell everything that you have relating</p> <p>10 to these three areas?</p> <p>11 A. I'm sorry, can you -- let me</p> <p>12 just -- I just want to make sure that I'm</p> <p>13 clear as far as what three areas.</p> <p>14 Q. Pelvic mesh, pelvic organ</p> <p>15 prolapse and stress urinary incontinence.</p> <p>16 A. Counselor, I'm sorry, can</p> <p>17 you tell me why pelvic mesh is relevant</p> <p>18 to an analysis of the -- of the TVT</p> <p>19 design? Because that's a completely</p> <p>20 different disease state.</p> <p>21 Q. I'm not talking about the</p> <p>22 disease state. And I ask the questions.</p> <p>23 But I'm happy to answer that.</p> <p>24 A. Yes.</p>

14 (Pages 50 to 53)

Marc Toggia, M.D.

Page 54	Page 56
<p>1 Q. The TVT uses the same 2 material that's used in other pelvic mesh 3 products, correct? 4 MR. SNELL: Objection. 5 Overbroad. 6 THE WITNESS: That was not 7 part of my analysis. My analysis 8 was on the TVT design and safety. 9 BY MS. THOMPSON: 10 Q. But I'm asking the 11 questions. And I'm asking you the 12 question. 13 Does the TVT use the same 14 material that's used in other pelvic mesh 15 devices? 16 A. The base -- 17 MR. SNELL: Same objection. 18 THE WITNESS: The base 19 material, they're both based upon 20 macroporous polypropylene mesh. 21 I'm not sure I would -- and 22 there's a wide variety of 23 fabrication and materials used. 24 I don't want you to think</p>	<p>1 clarifying that to say that, you know, 2 weight is a descriptor that's really 3 based upon surface area or volume. And 4 there's such a small volume of material 5 that we're talking about that I don't 6 know that anybody would specifically 7 state that that material was of a 8 specific weight. 9 Q. So it's your opinion that 10 you can't determine whether the mesh used 11 in the Gynecare TVTTM is heavyweight or 12 lightweight? 13 MR. SNELL: Objection. 14 Misstates. 15 THE WITNESS: That's not 16 what I said. 17 BY MS. THOMPSON: 18 Q. Then -- so someone can do it 19 but you can't, is that the answer? 20 MR. SNELL: Same objection. 21 THE WITNESS: I didn't say 22 that either. 23 BY MS. THOMPSON: 24 Q. Okay. My question, then,</p>
Page 55	Page 57
<p>1 that I think that, say, the mesh 2 that we use for pelvic organ 3 prolapse is simply the exact TVT 4 material expanded to a larger 5 size. 6 BY MS. THOMPSON: 7 Q. Well, let me ask you this: 8 What is the TVT material? 9 A. The Gynecare TVTTM is a Amid 10 Type I macroporous polypropylene mesh 11 that is of a knitted design. 12 Q. Is it lightweight or 13 heavyweight? 14 A. In my opinion, it is a 15 lightweight mesh. 16 Although I would say this, 17 weight of mesh is dependent upon the 18 volume or surface area. And I don't 19 really think that anybody -- excuse me, I 20 don't think that I could classify it 21 based on weight, given the fact that it's 22 a 1.1 centimeter strip of material. 23 So the short answer is that 24 it's lightweight. I am -- I am</p>	<p>1 is, is the mesh used in the Gynecare 2 TVTTM lightweight or heavyweight; choose 3 one of the two, or can't be determined? 4 A. The TVT -- the TVT device, I 5 would consider to be a lightweight 6 macroporous polypropylene mesh, with the 7 understanding that mesh weight, 8 technically, you have to consider the 9 volume of the material. 10 Q. Did Ethicon show you any 11 documents that described the TVT mesh as 12 not being macroporous and lightweight? 13 A. The documentation that I am 14 familiar with would support the -- what I 15 have said, TVT is a lightweight 16 macroporous mesh. 17 Q. And what are the documents 18 that you're using to base that opinion 19 on? 20 A. Everything that we are 21 referencing in the report, the materials 22 that we have included here today. 23 Q. Can you be more specific 24 than that?</p>

15 (Pages 54 to 57)

Marc Toggia, M.D.

Page 58	Page 60
<p>1 A. It would take -- it would</p> <p>2 take hours to go over all of those</p> <p>3 things.</p> <p>4 Q. Have you seen any Ethicon</p> <p>5 documents stating that the Gynecare TVTMM</p> <p>6 is large pore lightweight?</p> <p>7 A. I -- the TVT is lightweight</p> <p>8 and large pore.</p> <p>9 Q. And you're confident about</p> <p>10 that position?</p> <p>11 A. Counselor, I'm extremely</p> <p>12 confident in that statement.</p> <p>13 Q. I want to talk a little bit</p> <p>14 about your use of mesh products,</p> <p>15 including Ethicon products.</p> <p>16 I believe in your report you</p> <p>17 stated that you began using the TVT in</p> <p>18 1999; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. And were you trained by</p> <p>21 Ethicon in the use of that device?</p> <p>22 A. I was.</p> <p>23 Q. Do you remember who you were</p> <p>24 trained by?</p>	<p>1 Dr. Lucente. Dr. Lucente and I</p> <p>2 were having a conversation about</p> <p>3 things that he was working on. I</p> <p>4 asked if I could come up and</p> <p>5 become involved.</p> <p>6 I'm sure that there may or</p> <p>7 may not have been a relationship,</p> <p>8 at that time, between Ethicon and</p> <p>9 Dr. Lucente regarding my training.</p> <p>10 I certainly was not aware of that</p> <p>11 directly. This is something that</p> <p>12 Dr. Lucente and I, and other</p> <p>13 colleagues, would do for each</p> <p>14 other routinely.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Sure. So you didn't attend</p> <p>17 an Ethicon sponsored training session; is</p> <p>18 that what you're saying?</p> <p>19 MR. SNELL: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: To the best of</p> <p>22 my recollection, there may or may</p> <p>23 not have been a presentation</p> <p>24 given. My independent</p>
Page 59	Page 61
<p>1 A. I do.</p> <p>2 Q. Who is that?</p> <p>3 A. Dr. Vince Lucente, one of my</p> <p>4 colleagues.</p> <p>5 Q. And that training took place</p> <p>6 in early 1999; is that correct?</p> <p>7 A. I would be guessing, but I</p> <p>8 believe it might have been in May of</p> <p>9 1999. But I honestly can't tell you</p> <p>10 when -- when within the year it was.</p> <p>11 Q. And was that training done</p> <p>12 formally through Ethicon or did Dr.</p> <p>13 Lucente provide a more informal</p> <p>14 preceptorship to you?</p> <p>15 MR. SNELL: Objection.</p> <p>16 Vague.</p> <p>17 THE WITNESS: Dr. Lucente</p> <p>18 and I are close colleagues. It is</p> <p>19 not unusual for us to communicate</p> <p>20 and get together and work</p> <p>21 together.</p> <p>22 So, to be honest, it's --</p> <p>23 Ethicon did not come to me and</p> <p>24 say, we want you to go work with</p>	<p>1 recollection is that he and I</p> <p>2 performed maybe four or five cases</p> <p>3 together.</p> <p>4 But I honestly can't -- I</p> <p>5 can't tell you whether there was a</p> <p>6 formal or informal -- to be honest</p> <p>7 with you, given our relationships,</p> <p>8 those lines are blurred.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. Sure. And I understand.</p> <p>11 A. Yes.</p> <p>12 Q. I'm just trying to find out</p> <p>13 whether you were given the Ethicon oral</p> <p>14 presentation, for example, on the new</p> <p>15 device --</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. -- by an Ethicon</p> <p>19 representative.</p> <p>20 MR. SNELL: Objection.</p> <p>21 Vague.</p> <p>22 THE WITNESS: Not to my</p> <p>23 knowledge.</p> <p>24 BY MS. THOMPSON:</p>

16 (Pages 58 to 61)

Marc Toggia, M.D.

Page 62	Page 64
<p>1 Q. And did you participate in</p> <p>2 cadaver labs sponsored by Ethicon?</p> <p>3 A. Note, in the next ten years,</p> <p>4 I did a tremendous amount, or a variety</p> <p>5 of different things. I'm just not clear</p> <p>6 if we're referring to that one incidence</p> <p>7 or -- I mean, this was not a one-time</p> <p>8 experience.</p> <p>9 Q. Understood. I'm referring</p> <p>10 now to your training and I think we'll</p> <p>11 get, later, the training that you gave</p> <p>12 other doctors.</p> <p>13 A. Right.</p> <p>14 Q. But it sounds like, to me,</p> <p>15 and correct me if I'm wrong, you at least</p> <p>16 don't recall attending a formal training</p> <p>17 program sponsored by Ethicon --</p> <p>18 A. No, no.</p> <p>19 MR. SNELL: Objection.</p> <p>20 Overbroad.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. -- prior to using the TVT.</p> <p>23 MR. SNELL: Same objection.</p> <p>24 THE WITNESS: Maybe I</p>	<p>1 sounds like you had both, formal training</p> <p>2 from the company --</p> <p>3 A. Yes.</p> <p>4 Q. -- and a preceptorship or</p> <p>5 whatever you want to call --</p> <p>6 A. I wouldn't call it a</p> <p>7 preceptorship, but I had -- I mean,</p> <p>8 surgeons learn procedures from other</p> <p>9 surgeons.</p> <p>10 Q. Sure.</p> <p>11 A. Right.</p> <p>12 Q. And do you still use the</p> <p>13 Retropubic TVT device in your practice?</p> <p>14 A. Yes, I do.</p> <p>15 Q. Do you use other retropubic</p> <p>16 sling products?</p> <p>17 A. I do not.</p> <p>18 Q. So exclusive to TVT is what</p> <p>19 you're using now for a retropubic am</p> <p>20 synthetic sling?</p> <p>21 A. I have experience with a</p> <p>22 wide variety of devices. But if you were</p> <p>23 to come to me as a patient and we had</p> <p>24 determined that an anti-incontinence</p>
Page 63	Page 65
<p>1 didn't -- maybe I wasn't clear.</p> <p>2 I thought we were talking</p> <p>3 about what my first exposure was.</p> <p>4 But, of course, I had formal</p> <p>5 training from Ethicon prior to me</p> <p>6 independently performing the</p> <p>7 procedure in my practice.</p> <p>8 What I don't recall, and I'm</p> <p>9 really don't mean to be vague, is</p> <p>10 whether I did that training first</p> <p>11 and then worked with Dr. Lucente,</p> <p>12 whether they may have -- may have</p> <p>13 simultaneously occurred, or</p> <p>14 whether I first looked at the</p> <p>15 procedure with Dr. Lucente and</p> <p>16 then had the formal training.</p> <p>17 I do know that prior to</p> <p>18 doing the training with Dr.</p> <p>19 Lucente, I did consult with the</p> <p>20 company prior to the procedure's</p> <p>21 launch and received education at</p> <p>22 that level.</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Okay. Fair enough. So</p>	<p>1 procedure was appropriate, then the</p> <p>2 retropubic TVT is, 95 percent of the</p> <p>3 times, the retropubic procedure or</p> <p>4 midurethral-sling-based procedure that I</p> <p>5 would use.</p> <p>6 Q. Are you doing, currently,</p> <p>7 any transobturator slings?</p> <p>8 A. I do do transobturator</p> <p>9 slings.</p> <p>10 Q. What percentage of your</p> <p>11 practice, currently, is retropubic and</p> <p>12 what percentage transobturator?</p> <p>13 A. It's probably 95 percent</p> <p>14 retropubic and about 5 percent at the</p> <p>15 present time. It has varied over time.</p> <p>16 Q. And over the years, how many</p> <p>17 TVT or TVT Exact® products have you used?</p> <p>18 A. By my best estimates, I</p> <p>19 would say 2,500 TVT procedures, give me a</p> <p>20 wide margin of error of probably 300 in</p> <p>21 either direction, perhaps.</p> <p>22 Q. How do you keep track of</p> <p>23 which products you use?</p> <p>24 A. I have a very good memory.</p>

17 (Pages 62 to 65)

Marc Toggia, M.D.

Page 66	Page 68
<p>1 Q. So if I wanted to ask you</p> <p>2 exactly how many of a given product you</p> <p>3 have used, could you tell me?</p> <p>4 A. I could give you an</p> <p>5 approximate ballpark.</p> <p>6 Q. And how would you do that?</p> <p>7 A. Through a variety of</p> <p>8 methods. But, as I said, I've got a</p> <p>9 pretty good idea mentally. If you ask me</p> <p>10 how many TVT-Securs I did, I would tell</p> <p>11 you 60.</p> <p>12 Q. And that would come from</p> <p>13 your memory, correct?</p> <p>14 A. My memory. I'd have to go</p> <p>15 through some office records, some</p> <p>16 documentation elsewhere.</p> <p>17 Q. So what office records would</p> <p>18 you go through?</p> <p>19 A. We have billing data. You</p> <p>20 know, I am not telling you that these are</p> <p>21 things that are readily available to me,</p> <p>22 if you asked me, can I see this in the</p> <p>23 next, you know, hour or day.</p> <p>24 But, certainly, there are --</p>	<p>1 have to do to determine which -- what</p> <p>2 complications experienced as well?</p> <p>3 A. No.</p> <p>4 Q. How would we be able to</p> <p>5 determine what complications patients</p> <p>6 have experienced?</p> <p>7 MR. SNELL: Objection.</p> <p>8 Overbroad. Are you talking about</p> <p>9 his patients?</p> <p>10 MS. THOMPSON: Yes.</p> <p>11 THE WITNESS: I'm sorry,</p> <p>12 what was your question? I'm not</p> <p>13 sure I understood it.</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. How would we determine --</p> <p>16 A. You seem -- you seemed to</p> <p>17 have switched gears.</p> <p>18 Q. Well, I was just interested</p> <p>19 in determining how you figured out what</p> <p>20 product was used. And I'm also</p> <p>21 interested in how you figure out what</p> <p>22 complications patients experienced.</p> <p>23 And I'm asking you, how</p> <p>24 would we determine that?</p>
Page 67	Page 69
<p>1 there are internal things that we</p> <p>2 could -- you know, databases that would</p> <p>3 contain such records.</p> <p>4 Q. So you could go to your</p> <p>5 billing records and tell me whether a TVT</p> <p>6 or TVT Exact® was used?</p> <p>7 A. No, I don't think I could do</p> <p>8 it through billing records, obviously.</p> <p>9 Billing records wouldn't tell me that.</p> <p>10 Q. What other records would you</p> <p>11 use?</p> <p>12 A. We would have to pull the</p> <p>13 charts on every patient. And every --</p> <p>14 very procedure that's done carries an</p> <p>15 implant record. And so someone would sit</p> <p>16 there with approximately 2,500 charts and</p> <p>17 go through the implant records.</p> <p>18 And by looking at the lot</p> <p>19 number or model number, we would be able</p> <p>20 to tell -- I mean, obviously, the Exacts®</p> <p>21 would all be labeled as such and the TVTs</p> <p>22 and the Obturator would be labeled as</p> <p>23 such.</p> <p>24 Q. And is that what we would</p>	<p>1 A. I'm sorry, that's not what</p> <p>2 you asked me originally. That's a</p> <p>3 whole -- I would have to start from</p> <p>4 scratch to --</p> <p>5 Q. Okay.</p> <p>6 A. You've asked me how -- you</p> <p>7 asked me what products have I used and</p> <p>8 what percentage of products that I've</p> <p>9 used and how it would be that I would</p> <p>10 determine that number of products.</p> <p>11 Q. Yes.</p> <p>12 Now I'm asking you, how</p> <p>13 would you determine which complications</p> <p>14 occurred with various products?</p> <p>15 A. I would have to sit down and</p> <p>16 try and figure that out, counselor. I</p> <p>17 can't tell you off the top of my head</p> <p>18 that I have an accurate way of -- I mean,</p> <p>19 there may be ways, through the billing</p> <p>20 system, to capture certain complications</p> <p>21 based upon -- by diagnosis codes.</p> <p>22 Q. Let's go through other</p> <p>23 Ethicon products.</p> <p>24 Did you use the TVT-O at</p>

18 (Pages 66 to 69)

Marc Toggia, M.D.

Page 70	Page 72
<p>1 some point?</p> <p>2 A. I did.</p> <p>3 Q. About how many TVT-Os did</p> <p>4 you place?</p> <p>5 A. Approximately 2 to 300.</p> <p>6 Q. And when did you start using</p> <p>7 the TVT-O?</p> <p>8 A. To the best of my knowledge,</p> <p>9 I can't remember when -- the product</p> <p>10 launch was in 2005 or 2002? Whenever the</p> <p>11 product was launched, roughly about when</p> <p>12 I had used the TVT-O.</p> <p>13 Q. And how did you learn about</p> <p>14 the TVT-O?</p> <p>15 A. By that point in time, I</p> <p>16 was -- you know, we -- we attend certain</p> <p>17 scientific meetings, publications, the</p> <p>18 usual things that we do in the course of</p> <p>19 our -- of our practice, my role reviewing</p> <p>20 manuscripts for publications, my role as</p> <p>21 an editor of journals.</p> <p>22 I mean, there's a wide range</p> <p>23 of ways that topics like this were</p> <p>24 introduced to us.</p>	<p>1 the times, I'm a bit further along in</p> <p>2 that regard, and my -- you know, my -- I</p> <p>3 don't rely upon that relationship for</p> <p>4 that kind of information.</p> <p>5 Q. What Ethicon products were</p> <p>6 you involved in the design, as you've</p> <p>7 been referring to?</p> <p>8 A. Well, I was -- as I</p> <p>9 mentioned earlier, I was consulted on the</p> <p>10 original TVT Retropubic. I offered</p> <p>11 opinions on the Obturator product at some</p> <p>12 point in time, the TVT-Secur. I had</p> <p>13 significant involvement in the design of</p> <p>14 the TVT EXACT® product.</p> <p>15 Q. And would these have all</p> <p>16 been prior to the devices going to</p> <p>17 market?</p> <p>18 A. A combination. Not</p> <p>19 necessarily the same for each product.</p> <p>20 Q. But at least for the</p> <p>21 original TVT, you were consulted before</p> <p>22 the product was marketed, I believe you</p> <p>23 said; is that correct?</p> <p>24 A. I recall being a part of</p>
Page 71	Page 73
<p>1 Q. Did you get information from</p> <p>2 sales reps?</p> <p>3 A. On the TVT-O? Eventually.</p> <p>4 I can't tell you that that was maybe</p> <p>5 my -- if that was my first exposure or</p> <p>6 not. To be completely frank, at my level</p> <p>7 of involvement with the company, sales</p> <p>8 reps are not a -- that's not a source</p> <p>9 that I would utilize a high degree. I</p> <p>10 usually find out -- I'm educated on stuff</p> <p>11 before a sales rep is probably aware of</p> <p>12 it.</p> <p>13 And, of course, I don't --</p> <p>14 I'm not at liberty to discuss that with</p> <p>15 sales reps.</p> <p>16 Q. What -- what are you not at</p> <p>17 liberty to discuss with sales reps?</p> <p>18 A. Well, for example, if I'm</p> <p>19 involved in the -- if I've been consulted</p> <p>20 upon the design of a new product, you</p> <p>21 know, sales reps are not well versed or</p> <p>22 maybe not aware of what things are in</p> <p>23 development.</p> <p>24 I'm just saying that most of</p>	<p>1 expert focus groups that discussed the</p> <p>2 concept that would look at towards am</p> <p>3 what was the utility, the market need,</p> <p>4 the viability.</p> <p>5 Because I'm an educator,</p> <p>6 it's likely that I was asked questions</p> <p>7 regarding about -- about that.</p> <p>8 Q. So at least for the sling</p> <p>9 products, you were involved in the design</p> <p>10 of the original TVT, the TVT-O, TVT-Secur</p> <p>11 and TVT EXACT®; is that correct?</p> <p>12 A. I don't -- I don't know that</p> <p>13 I would say design in those. I was</p> <p>14 involved in the design for the TVT</p> <p>15 EXACT®.</p> <p>16 The TVT product was already</p> <p>17 set to be launched, so, clearly, it had</p> <p>18 already been designed. I'm just saying</p> <p>19 that I had input and my opinion was</p> <p>20 sought out prior to the product being</p> <p>21 launched.</p> <p>22 Q. For which of those products</p> <p>23 were you actually paid by Ethicon to give</p> <p>24 your opinions as to the devices?</p>

19 (Pages 70 to 73)

Marc Toggia, M.D.

Page 74	Page 76
<p>1 A. To the best of my knowledge, 2 I provided paid consultant services on 3 all those products. 4 Q. And what about Ethicon's 5 prolapse products, were you involved in 6 the design of any of those? 7 A. I mean, I had involvement in 8 many products, some of which never saw 9 the light of day, as well as the TVT 10 Prolift family of products. 11 Q. So the PROLIFT® Anterior? 12 A. Correct. 13 Q. PROLIFT® Posterior? 14 A. Correct. 15 Q. PROLIFT® Total? 16 A. Yes. 17 Q. Do you remember the names of 18 any of the other devices that you 19 consulted on? 20 A. I could probably dredge that 21 from my memory, yes. 22 Q. All right. I'll take it. 23 A. I believe there was a 24 product called the V-Tac product. I</p>	<p>1 A. To the best of my knowledge, 2 yes. 3 Q. Are you the type of doctor 4 that likes to see data before using a 5 product? 6 MR. SNELL: Objection. 7 Vague. 8 THE WITNESS: I would 9 characterize myself as somebody 10 who puts a great deal of 11 importance on sound scientific 12 principles. Certainly, when 13 high-quality data is available, it 14 is given the weight that it 15 deserves. 16 At different -- you know, 17 the area of urogynecology has 18 evolved tremendously in the past 19 20 years. I was very fortunate to 20 be within this field at very 21 early -- at a very early phase. 22 So there are certainly procedures, 23 techniques, theories that I was 24 involved with very early on, and,</p>
Page 75	Page 77
<p>1 believe there was a product called 2 PROSIMATM product. Obviously, the 3 PROLIFT® +M was simply a modification of 4 the original PROLIFT® procedure. 5 There was a product that I 6 was the originator of the concept, the 7 proof of concept, the initial engineering 8 that had to do with a post anal sling for 9 treatment of a different pelvic floor 10 disorder known as anal incontinence. 11 Q. Did that product ever have a 12 name? 13 A. You know, it had a name in 14 development. The product never came to 15 market. 16 Q. What was the name in 17 development? 18 A. In development, we would 19 refer to that product as the Post-Anal 20 Sling Surgery or PAS. 21 Q. And to the best of your 22 recollection, were you a paid consultant 23 for your involvement in each of those 24 products as well?</p>	<p>1 obviously, data comes a little bit 2 later. 3 BY MS. THOMPSON: 4 Q. And you actually were part 5 of a study comparing the retropubic TVT 6 to TVT-Secur; is that correct? 7 A. That is correct. 8 Q. Before beginning that study, 9 did you have any data on the TVT-Secur? 10 A. Yes. 11 Q. What was that data? 12 A. So there was the -- as is 13 typical, there are always safety and 14 efficacy studies that are put before -- 15 I'm sorry, let me rephrase that. 16 There was preliminary 17 published data, I believe, from the UK or 18 Europe about the initial design and 19 development for the TVT-Secur. And that 20 would have been some of the data that we 21 were considering. 22 The reason for doing the 23 trial, of course, is that we already had 24 a procedure that was widely practiced and</p>

20 (Pages 74 to 77)

Marc Toggia, M.D.

Page 78	Page 80
<p>1 widely accepted that had a tremendous 2 amount of data supporting its long-term 3 safety and effectiveness. 4 And with a new product 5 available, we want to specifically 6 compare apples to apples. 7 Q. So it's your position that 8 there was published literature on the 9 safety and efficacy of the TVT-Secur 10 before it was launched in the U.S.? 11 A. I don't believe that's what 12 I said. 13 Q. Okay. Was there safety and 14 efficacy -- published safety and efficacy 15 studies on the TVT-Secur before it was 16 launched in the U.S.? 17 A. I don't have independent 18 recollection, as I sit here now, as far 19 as the timing of one versus the other. 20 Q. So you don't know, one way 21 or the other, whether there were any 22 published data on the TVT-Secur -- 23 A. I'm not saying -- 24 Q. -- before it was launched?</p>	<p>1 stress incontinence and that there was a 2 newer procedure that was FDA approved and 3 that it was our interest in comparing the 4 two products, looking at safety, 5 effectiveness, differences in recovery, 6 everything from activity, the amount of 7 pain medication someone was to take, 8 because we wanted to be able to 9 independently compare the two procedures 10 side by side in a scientific manner that 11 would attempt to minimize bias. 12 Q. Did you tell patients that 13 the TVT-Secur had never been used in a 14 woman, prior to launching? 15 MR. SNELL: Objection. 16 Foundation. 17 THE WITNESS: I don't 18 recall. I don't recall that I -- 19 that I said that, no. 20 BY MS. THOMPSON: 21 Q. Was the TVT-Secur FDA 22 approved? 23 A. Yes. To the best of my 24 knowledge, the TVT-Secur was FDA</p>
Page 79	Page 81
<p>1 A. I'm not saying that I don't 2 know. I'm just saying that as I sit here 3 in conversing with you now, I cannot, in 4 my mind, say, okay, the TVT-Secur was 5 launched on this particular date and the 6 safety -- excuse me, a clinical trial was 7 published before or after. 8 Q. What did you tell the 9 patients that enrolled in that study 10 about the safety and effectiveness of the 11 TVT-Secur? 12 A. Well, I mean, the patients 13 underwent standardized and uniform 14 informed consent that was the same across 15 the entire -- the entire study. This 16 consent was, of course, approved -- at 17 our -- at our institution it was approved 18 by our own internal -- our IRB. 19 As far as the exact language 20 of that, I can't tell you. But, you 21 know, essentially, we would explain to a 22 patient that there was an established 23 procedure that was widely practiced and 24 was an accepted first-line therapy for</p>	<p>1 approved. 2 Q. I want to go back to your 3 relationship with the Ethicon sales reps. 4 Do you recall who the sales 5 rep was that called on you here in 6 Philadelphia when you first began using 7 the TVT? 8 A. There were several. I don't 9 know who came first. 10 Q. Do you remember any of the 11 sales reps that have called on you here 12 in Philadelphia for Ethicon? 13 A. Yes. 14 Q. Which ones? 15 A. There was a woman, Eileen 16 Ghenn. There was -- 17 Q. I'm sorry, how do you 18 spell Ghenn? 19 A. Ghenn? G-H-E-N-N, and 20 that's a guess. 21 I believe there was a 22 Marty -- I can't remember his last name. 23 There was another gentleman whose first 24 name was Tom. There was a woman by the</p>

21 (Pages 78 to 81)

Marc Toggia, M.D.

Page 82	Page 84
<p>1 name of Kathleen Feeney. There was, more 2 recently, a gentleman whose name escapes 3 me. 4 There were -- there were 5 half a dozen or more. I'm sorry. 6 Q. And of the ones that you 7 remember their names, can you tell me, 8 for example, Ms. Ghenn, when did she call 9 on you for Ethicon? 10 A. I honestly couldn't tell you 11 the dates. 12 Q. Is she still an Ethicon 13 sales rep and still calling on you? 14 A. No. 15 Q. And how about Marty, do you 16 recall the time frame where he called on 17 you as an Ethicon sales rep? 18 A. He was in -- he would have 19 been in the beginning. I can't tell you 20 that he was 1999, 2000, 2001. My 21 recollection was within the first three 22 or four years, I seemed to have a 23 different rep every year. 24 There's another woman by the</p>	<p>1 with? 2 A. No, there is not. 3 Q. And Ms. Feeney is no longer 4 working for Ethicon; is that correct? 5 A. That's correct. 6 Q. And Kathy, do you remember 7 when Kathy -- 8 A. No. 9 Q. -- was a sales rep? 10 Generally, did you have a 11 good relationship with the sales -- 12 Ethicon sales reps, including the ones 13 that you mentioned? 14 A. Some better than others. 15 Q. Which ones were they better 16 with? 17 A. Again, these are transient 18 people in my life. I mean, Kathleen 19 Feeney and I had a reasonable 20 relationship. Eileen Ghenn and I, not so 21 much, that I recall. 22 I mean, there's really 23 nothing of any great meaning to these 24 relationships either way.</p>
Page 83	Page 85
<p>1 name of Kathy, I believe. 2 I'm sorry. 3 Q. That's okay. 4 And Tom, do you remember 5 when Tom was a sales rep? 6 A. Counselor, I'm sorry, let 7 me -- I can't give you specifics on any 8 of these people. 9 Q. And that's fine. It's fine 10 to say -- 11 A. Right. I don't recall. 12 Q. -- I don't recall, no, or I 13 don't remember. 14 And how about Ms. Feeney, do 15 you remember when she was a sales rep? 16 A. To the best of my 17 recollection, Ms. Feeney was my rep for 18 the longest period of time. Time frame 19 wise, it would -- I would be guessing. I 20 would say 2005 to 2009, for example. It 21 might have been a period of two to four 22 years. I honestly don't know. 23 Q. How about currently, is 24 there a sales rep that you're familiar</p>	<p>1 Q. Did you have loyalty to the 2 sales reps? 3 A. No, not at all. 4 MR. SNELL: If you're going 5 to move to a different topic, can 6 we take a break? 7 MS. THOMPSON: Yeah, this is 8 a good time for a break. 9 MR. SNELL: We've been going 10 about an hour and-a-half. 11 MS. THOMPSON: Yes. 12 VIDEO TECHNICIAN: We are 13 off the record. The time is 2:41 14 p.m. 15 - - - 16 (Whereupon, a brief recess 17 was taken.) 18 - - - 19 VIDEO TECHNICIAN: This 20 marks the beginning of Video 21 Number 2. We are back on the 22 record. The time is 3:00 p.m. 23 BY MS. THOMPSON: 24 Q. Dr. Toggia, I do have a few</p>

22 (Pages 82 to 85)

Marc Toggia, M.D.

Page 86	Page 88
<p>1 more questions about sales reps. 2 A. Yes. 3 Q. How did you typically 4 contact the sales rep? 5 A. I would say most frequently 6 they came to my office, and we would have 7 a face-to-face discussion. I'm sure that 8 we had e-mail contact. There was 9 probably cell phone contact with some, 10 when cell phones were, you know, in 11 existence and sort of widely used to for 12 that reason. 13 Q. Did you ever use sales reps' 14 personal e-mails? 15 A. I used whatever e-mails they 16 gave me. So, yes, I'm -- it's -- if 17 they -- maybe if they e-mailed me from 18 their personal e-mail, my reply would 19 simply be back to them. I can't tell you 20 that I would distinguish between the two. 21 Q. And what about personal cell 22 phone numbers? 23 A. I honestly can't tell you 24 whether they had company cell phones,</p>	<p>1 Q. I'm going to hand you 2 Exhibit Number 4. I'll give you a minute 3 to look at that. 4 A. Okay. 5 MR. SNELL: What number are 6 we on? 7 MS. THOMPSON: 4. 8 BY MS. THOMPSON: 9 Q. Can you describe this e-mail 10 chain with Kathleen Feeney, one of the 11 sales reps that you told us about 12 earlier? 13 A. Uh-huh. I don't -- I can't 14 tell you that I have -- it seems to me 15 like there is a variety of different 16 things being discussed over here. 17 Q. What were the dates of these 18 e-mails? 19 A. 2009. 20 Q. March of 2009? 21 A. Yes. 22 Q. Beginning at the bottom of 23 the first page? 24 A. Yes.</p>
Page 87	Page 89
<p>1 personal cell phones. I gave -- again, 2 whatever contact information might have 3 been presented to me on a business card, 4 I would -- I would assume -- I mean, I 5 was assuming I was calling a business 6 cell. 7 Q. Did you consider your 8 relationship with the sales rep 9 professional? 10 A. Yes. 11 Q. Was the relationship always 12 appropriate with the sales reps, in your 13 opinion? 14 A. Yes. 15 - - - 16 (Whereupon, Exhibit 17 Toggia-4, 3/19/09 E-mail from 18 Marc Toggia to Kathleen Feeney; 19 Subject: Re: These events were 20 approved 3.25 proctorship and 4.21 21 preceptorship, was marked for 22 identification.) 23 - - - 24 BY MS. THOMPSON:</p>	<p>1 Q. Could you just read what is 2 contained in these e-mails between you 3 and Ms. Feeney? 4 A. I'm -- she says, I am so -- 5 and then she uses a word that I'm just 6 not going to mention out loud -- He's 7 nowhere from being done and wants no 8 help. 9 I think she's referring to 10 another surgeon that she was probably in 11 a case with. I mean, there's just no 12 context here. I'm sorry. 13 Q. Well, this e-mail is from 14 you. 15 A. I'm sorry? 16 Q. This e-mail is from you on 17 Thursday, March 19th, 10:46. 18 A. Okay. 19 I don't know -- I don't know 20 what -- I mean, it sounds like I was -- I 21 was scrubbed in with somebody else. I 22 honestly couldn't tell you what this -- 23 what the context of that was. 24 Q. So would you read that</p>

23 (Pages 86 to 89)

Marc Toggia, M.D.

Page 90	Page 92
<p>1 again, knowing that that's you writing 2 the e-mail. 3 A. Yes. So, apparently, this 4 says, I am so f'ed, he's nowhere being 5 done and wants no help. You and I will 6 be having a lunch before my case. 7 Q. So you're comfortable 8 putting that word in an e-mail to the 9 sales rep, although you're not 10 comfortable stating the word here in this 11 deposition; is that correct? 12 A. That is correct. 13 MR. SNELL: Objection. 14 Argumentative. 15 Go ahead. 16 BY MS. THOMPSON: 17 Q. Okay. Go ahead and read the 18 next e-mail up. 19 A. Call me. Pulling up now. 20 Do you want to meet me outside in front? 21 Q. That's from Ms. Feeney to 22 you? 23 A. Yes. 24 Q. And then the next one?</p>	<p>1 though. 2 BY MS. THOMPSON: 3 Q. Am I reading that correctly? 4 A. I don't think so. I don't 5 know -- no. I don't -- I don't 6 appreciate what you're implying. And I 7 can tell you for sure that this has 8 nothing to do with -- with that. 9 Q. Well, tell -- give me 10 another explanation for why it would be 11 No, maybe you, though, in response to, 12 Can you do her downstairs? 13 A. Well -- 14 MR. SNELL: Objection. 15 Argumentative. 16 THE WITNESS: -- "do her" 17 has nothing to do -- has nothing 18 to do with sex, I can guarantee 19 you that, on any level. 20 BY MS. THOMPSON: 21 Q. All right. Provide me the 22 alternative explanation. 23 A. I don't have the context of 24 what this is.</p>
Page 91	Page 93
<p>1 A. Still have not started. 2 Q. And then the one after that, 3 from Ms. Feeney? 4 A. Can you do her downstairs? 5 Q. And then the last one from 6 you to Ms. Feeney? 7 A. On top? 8 Q. Yes. 9 A. The first one? 10 Q. Yes. 11 A. No, maybe, though. Your 12 girlfriend Christine is here and won't 13 leave. I think she liked her last 14 suggestion too much. 15 Q. I don't think you read the 16 first sentence correctly. 17 MR. SNELL: I'm going to 18 object. He did read it. 19 MS. THOMPSON: Could you -- 20 no. He read, no, maybe, though, 21 your girlfriend Christine. 22 And it actually reads, the 23 response to, Can you do her 24 downstairs, is, No, maybe you,</p>	<p>1 Q. Well, these are your e-mails 2 with Ms. Feeney. 3 What context do you need? 4 A. I don't know what she's -- I 5 don't know what -- I mean, obviously, 6 there was a -- there's a conversation 7 going on that is not captured in the bulk 8 of this -- of this discussion. 9 I mean, there's hours and 10 hours that go -- they may not even be 11 related. I mean, there's hours that are 12 between the two. 13 Q. Was there other 14 correspondence during that hours -- those 15 hours? 16 A. I would have no idea. 17 Q. And who is Christine? 18 A. I think it's another -- I 19 think it's a sales rep for -- like, a 20 pharmaceutical sales rep or a different 21 sales rep. I have no idea who it is. 22 Q. Do you think these e-mails 23 with Ms. Feeney are appropriate? 24 A. I can't tell you that I</p>

24 (Pages 90 to 93)

Marc Toggia, M.D.

Page 94	Page 96
<p>1 recall -- I don't know the context. And 2 I don't know that these are related. And 3 I don't think that they're strung in the 4 manner that you're insinuating. 5 Q. Do you think these e-mails 6 are professional? 7 A. I don't think, in this line 8 of conversation, we were discussing 9 anything related to her -- to anything 10 that -- I don't know. I don't know what 11 these were referring to, to be honest 12 with you. 13 Q. Did you have any personal 14 phone calls with Ms. Feeney? 15 A. Yes. I mean, I'm sure that 16 I spoke with Ms. Feeney on a variety of 17 things. She may have told me things 18 about her kids, she may have had ideas 19 about job opportunities that she was 20 interviewing for. I'm sure she asked me 21 about friends, in terms of their health 22 or, you know, she had a sick grandmother 23 or something. 24 I mean, you know, people</p>	<p>1 THE WITNESS: Right. And I 2 don't appreciate it either. 3 MR. SNELL: If you're here 4 to ask him about his opinions, why 5 don't you do that? Unless you're 6 trying to, like, just be totally 7 argumentative -- 8 MS. THOMPSON: And I 9 didn't -- 10 MR. SNELL: -- that's what 11 you're doing. 12 MS. THOMPSON: -- insinuate 13 anything -- 14 MR. SNELL: Yes, you did. 15 MS. THOMPSON: -- or even 16 mention sex. He did. 17 MR. SNELL: Yes, you did. 18 MS. THOMPSON: Did I 19 anything about sex? I wanted him 20 to read the sentence, and he left 21 out -- it's the only thing he's 22 misread today. I was just curious 23 if he knew why he did that. 24 MR. SNELL: To the best of</p>
Page 95	Page 97
<p>1 will -- as a physician, people will ask 2 you, you know, personal questions. And, 3 certainly, as a gynecologist, I suspect 4 that I'm probably asked more personal 5 questions, you know. 6 Q. Why did you misread that 7 sentence when I asked you to read it? 8 A. Counselor, I did not misread 9 that. 10 MR. SNELL: Objection. Hold 11 on. Hold on. That's 12 argumentative. 13 MS. THOMPSON: I'm just 14 curious -- 15 MR. SNELL: That's 16 argumentative. 17 MS. THOMPSON: -- about a 18 question. 19 MR. SNELL: That's 20 argumentative. 21 THE WITNESS: To the best -- 22 MR. SNELL: And your -- he's 23 already told your insinuation is 24 not whole --</p>	<p>1 my knowledge, I read that sentence 2 exactly. 3 BY MS. THOMPSON: 4 Q. Well, you know that you did 5 not read it exactly, right? 6 MR. SNELL: Objection. 7 BY MS. THOMPSON: 8 Q. Because we read it back to 9 you from the transcript. 10 MR. SNELL: Argumentative. 11 THE WITNESS: Counselor, let 12 me state this clearly. I read 13 that sentence exactly. Maybe you 14 did not hear me read that exactly. 15 MS. THOMPSON: Okay. I can 16 pursue that. 17 Court reporter, could you 18 please read back Dr. Toggia's 19 answer when I asked the question 20 to read the e-mail from himself to 21 Ms. Feeney at the top of the page? 22 MR. SNELL: I'm going to 23 object. This is all asked and 24 answered and covered. I'm sorry.</p>

25 (Pages 94 to 97)

Marc Toggia, M.D.

Page 98	Page 100
<p>1 MS. THOMPSON: Are you going 2 to instruct him not to answer? He 3 said he -- 4 MR. SNELL: I'm not 5 instructing him not to answer. 6 He's told you three times. 7 MS. THOMPSON: Then he can 8 answer my question that I just 9 asked. 10 Amanda, if you could go 11 ahead and read the question and 12 answer, please. 13 - - - 14 (Whereupon, the court 15 reporter read the following part 16 of the record: 17 "Question: And then the 18 last one from you to Ms. Feeney? 19 "Answer: On top? 20 "Question: Yes. 21 "Answer: The first one? 22 "Question: Yes. 23 "Answer: No, maybe, though. 24 Your girlfriend Christine is here</p>	<p>1 BY MS. THOMPSON: 2 Q. I'm going to hand you 3 another e-mail, also with Ms. Feeney. 4 Can you identify this 5 e-mail? 6 A. This appears to be an e-mail 7 from Kathleen Feeney to Cindy Pypcznski. 8 Q. Would you go ahead and read 9 that, please? 10 A. Cin, notice the totally 11 different tone. Also note the timing of 12 this e-mail after I had it out with him 13 on the phone. Not regarding this, of 14 course, as you saw. Again, please don't 15 share this with anyone, as he is a great 16 guy, friend and surgeon. 17 Q. Who is she referring to when 18 she states that she had it out with him 19 on the phone? 20 A. I don't know. 21 Q. But it follows an e-mail 22 that you sent to her, correct? 23 A. I don't know if there was 24 anything in between. Again, the</p>
Page 99	Page 101
<p>1 and won't leave. I think she 2 liked your last suggestion too 3 much.") 4 - - - 5 BY MS. THOMPSON: 6 Q. Is it still your position 7 that you read that sentence -- that 8 e-mail correctly? 9 A. To the best of my knowledge, 10 I think I answered that. 11 Q. Okay. 12 A. Again, I would point out 13 that there is -- one of these -- the 14 initial one is 13:24 and the one above it 15 is 19:19. 16 Q. Okay. You answered my 17 question. 18 - - - 19 (Whereupon, Exhibit 20 Toggia-5, 10/23/08 E-mail from 21 Kathleen Toggia to Cindy 22 Pypcznski; Subject: FDA Toggia, 23 was marked for identification.) 24 - - -</p>	<p>1 difference in times is dramatic. 2 Q. My question is just this 3 was -- 4 A. It's a different date, as a 5 matter of fact. 6 Q. This was provided to us as 7 an e-mail chain. 8 So it does follow an e-mail 9 that you sent to Ms. Feeney, correct? 10 A. I don't know. 11 Q. Would you please read -- 12 what's the subject of the e-mail from Ms. 13 Feeney to Cindy? 14 A. It says, FDA, Toggia. 15 Q. Now, if you would look at 16 the e-mail from you to Ms. Feeney, and 17 the subject is, Stuff. 18 A. Correct. 19 Q. And it discusses the FDA, 20 correct? 21 A. Yes. 22 Q. And this e-mail was provided 23 as an e-mail chain. 24 Would it be a reasonable</p>

26 (Pages 98 to 101)

Marc Toggia, M.D.

Page 102	Page 104
<p>1 assumption to make that it was referring 2 to your e-mail below? 3 MR. SNELL: Objection. 4 Calls for speculation. Lacks 5 foundation. Calls for a 6 state-of-mind opinion. 7 MS. THOMPSON: Are you 8 suggesting that Ethicon produced 9 two unrelated e-mails on the 10 same -- 11 MR. SNELL: No. You're 12 asking him to speculate about what 13 Kathleen Feeney did, sending 14 something to somebody else with a 15 different subject line, a whole 16 different day later, and you're 17 asking him to speculate that one 18 is connected to the other; when 19 he's already testified, asked and 20 answered, that he can't make that 21 connection. 22 MS. THOMPSON: Okay. 23 BY MS. THOMPSON: 24 Q. So you sent an e-mail to Ms.</p>	<p>1 my knowledge, this has absolutely 2 nothing to do with TVT or -- 3 BY MS. THOMPSON: 4 Q. I just asked you to read -- 5 read -- 6 A. -- or the design of TVT. 7 Q. Excuse me. Dr. Toggia, I 8 just asked you -- 9 A. Yes. 10 Q. -- to read your e-mail from 11 you to Ms. Feeney. 12 MR. SNELL: You can read it. 13 THE WITNESS: Thanks for the 14 referral. Sorry you have had such 15 a tough week. You know I always 16 have your back. The FDA warning 17 is a big bummer, but I don't think 18 it will affect you much. We will 19 make some mild changes in how we 20 counsel folks. It would be good 21 if we could figure out how much of 22 this is apogee versus other stuff. 23 Could use it as a spin versus -- I 24 don't know what -- gurt, or as an</p>
Page 103	Page 105
<p>1 Feeney that was -- 2 MS. THOMPSON: And please 3 object to form only. 4 BY MS. THOMPSON: 5 Q. You sent an e-mail to Ms. 6 Feeney that was -- that concerned the 7 FDA, and Ethicon has produced an e-mail 8 that is in the same e-mail chain that's 9 from Ms. Feeney to Cindy, that's 10 entitled -- it's titled, FDA Toggia. 11 And she says, Also note the 12 timing of this e-mail after I had it out 13 with him on the phone. Not regarding 14 this, of course, as you saw. Again, 15 please don't share with anyone, as he is 16 a great guy friend and surgeon. 17 Why don't you go ahead and 18 read the e-mail that you sent to Ms. 19 Feeney? 20 MR. SNELL: I'm going to 21 object. And move to strike what 22 she just did. There's not even a 23 question there. 24 THE WITNESS: To the best of</p>	<p>1 excuse to do a few informal 2 dinners with key clients to help 3 diffuse. I do think there is some 4 room -- some -- there are some 5 folks who are at higher risk for 6 pain that it is best to avoid, 7 hence the small drop off in our 8 numbers. Hopefully, your company 9 will lower your projections. I 10 think I may blow off Chicago and 11 just relax. 12 BY MS. THOMPSON: 13 Q. What was the FDA warning 14 that you were referring to in this 15 e-mail? 16 A. Well, it's dated 2008, so I 17 am -- I am guessing, and it would be a 18 pure guess that it was an FDA warning -- 19 the first FDA safety letter that spoke 20 about vaginal mesh kits. 21 Q. And in this e-mail, you felt 22 that some mild changes in how you 23 counseled folks would be the way to 24 address that FDA warning?</p>

27 (Pages 102 to 105)

Marc Toggia, M.D.

Page 106	Page 108
<p>1 A. No. Because we were already 2 addressing the FDA warning, the mild 3 change was the fact that we would include 4 the words, "the FDA has issued." 5 But we had always been, with 6 these kits, very up front with our 7 patients and would say, this is a newer 8 procedure, it represents only one -- 9 basically, everything that the FDA stated 10 in there, we were independently doing 11 prior to the FDA's recommendations. 12 The minor change would have 13 been that we would now say that there was 14 an FDA and we were provided that 15 reference. 16 Q. Okay. And then you mention 17 that there are some folks at higher risk 18 for pain that's best to avoid. 19 Did Ethicon ever tell you 20 that there were patients who would be 21 high risk for pain that you should avoid 22 the use of mesh kits? 23 A. I would not rely upon 24 Ethicon to tell me that kind of stuff.</p>	<p>1 Q. Was she fired? 2 A. I was never told the reason 3 why she stopped working for the company. 4 Q. If I told you it was in 5 2009, would you have any reason to 6 disagree with that? 7 MR. SNELL: Objection. 8 Foundation. 9 THE WITNESS: No. 10 BY MS. THOMPSON: 11 Q. I'll give you another e-mail 12 with Ms. Feeney. 13 - - - 14 (Whereupon, Exhibit 15 Toggia-6, 4/27/09 E-mail from 16 Marc Toggia to Kathleen Feeney; 17 Subject: RE: Itinerary for TVT 18 Proctorship, was marked for 19 identification.) 20 - - - 21 MR. SNELL: Is this 6? 22 MS. THOMPSON: I believe so. 23 THE WITNESS: Yes. 24 BY MS. THOMPSON:</p>
Page 107	Page 109
<p>1 We were -- as we sort of 2 developed through the procedure, we 3 both -- we both -- we both became more 4 aware of groups of patients in whom the 5 product was appropriate, groups of 6 patients in whom we thought the procedure 7 was not ideal. 8 And we -- you know, all 9 surgical procedures have elemental 10 risks -- 11 Q. Excuse me, if you can just 12 ask my -- answer my question, we'll move 13 along a lot faster. 14 A. I'm sorry? 15 Q. The question was, did 16 Ethicon tell you that there were patients 17 at high risk for pain that should not use 18 the kits? 19 A. No. 20 Q. Thanks. 21 Do you know when Ms. Feeney 22 left Ethicon? 23 A. I don't know. 2009. I'm 24 just guessing. 2011. I don't know.</p>	<p>1 Q. Would you just read the top 2 e-mail that's from you to Ms. Feeney in 3 April of 2009? 4 A. I found the name for 5/28. 5 It is Finkelstein. Sorry for this. I 6 know it seems unimportant. I guess I'm 7 just trying to keep myself distracted. 8 Good luck. Regardless of what happens, 9 you know that I think you're the best and 10 have no questions regarding your moral 11 integrity. Please call me afterwards. 12 Q. Can you tell us about the 13 context of this e-mail? 14 A. I honestly have no idea what 15 any of this refers to. 16 Q. So you sent Ms. Feeney an 17 e-mail about not having questions about 18 her moral integrity, but you can't 19 remember what that could have referred 20 to? 21 A. It's dated in 2009. She may 22 have left the company, was leaving the 23 company, was concerned she was leaving 24 the company. I was just offering some --</p>

28 (Pages 106 to 109)

Marc Toggia, M.D.

Page 110	Page 112
<p>1 some support.</p> <p>2 Q. But you don't remember</p> <p>3 anything --</p> <p>4 A. I mean --</p> <p>5 Q. -- more than that?</p> <p>6 A. She could have -- she could</p> <p>7 have questioned herself or said -- you</p> <p>8 know, this may not have even been work</p> <p>9 related. She could have been having</p> <p>10 problems at home, and I was just trying</p> <p>11 to -- to reassure her.</p> <p>12 I honestly don't. I</p> <p>13 honestly don't. I don't know who</p> <p>14 Finkelstein is. I don't know what the</p> <p>15 name applies to. I don't know what any</p> <p>16 of this is in the context of, I'm sorry.</p> <p>17 MS. THOMPSON: We'll request</p> <p>18 any e-mails between you and Ms.</p> <p>19 Feeney on her personal e-mail.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. And if Ms. Feeney gives an</p> <p>22 explanation for this e-mail, would you</p> <p>23 have any reason to -- or basis to</p> <p>24 disagree with her interpretation?</p>	<p>1 MR. SNELL: Objection.</p> <p>2 Calls for speculation.</p> <p>3 THE WITNESS: It's possible</p> <p>4 that her recollection may give me</p> <p>5 further information. I don't</p> <p>6 know.</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. When you began using the TVT</p> <p>9 in 1999, what did you provide patients,</p> <p>10 when you were getting informed consent</p> <p>11 for the use of the product, regarding</p> <p>12 risks?</p> <p>13 A. So we were very -- I was</p> <p>14 very clear with my patients, at the time,</p> <p>15 what the traditional therapies, surgeries</p> <p>16 were, what the elemental risks were, the</p> <p>17 fact that -- that in the previous ten</p> <p>18 years there was a paradigm shift in the</p> <p>19 understanding of what caused stress</p> <p>20 incontinence, how stress incontinence</p> <p>21 might be treated differently --</p> <p>22 Q. Dr. Toggia, I'm sorry to</p> <p>23 interrupt, but I'm just asking you what</p> <p>24 you told patients about the risks</p>
Page 111	Page 113
<p>1 MR. SNELL: Objection. Hold</p> <p>2 on. Calls for speculation. Lacks</p> <p>3 foundation.</p> <p>4 MS. THOMPSON: Form is fine.</p> <p>5 MR. SNELL: No, but I'm</p> <p>6 articulating the form, that's what</p> <p>7 it is. There's no problem with</p> <p>8 that.</p> <p>9 MS. THOMPSON: I don't</p> <p>10 believe -- I don't think that's</p> <p>11 the case.</p> <p>12 Yes.</p> <p>13 BY MS. THOMPSON:</p> <p>14 Q. Would you have any reason to</p> <p>15 disagree?</p> <p>16 A. I -- I might. I don't -- I</p> <p>17 honestly don't know what -- what we were</p> <p>18 referring to here. These are -- these</p> <p>19 are random snippets, you know. There's</p> <p>20 no context.</p> <p>21 Q. Well, if -- if you don't</p> <p>22 recall, then you would not be able --</p> <p>23 have any basis to disagree with her</p> <p>24 recollection, then?</p>	<p>1 associated with TVT?</p> <p>2 A. I'm telling you.</p> <p>3 MR. SNELL: Objection. He's</p> <p>4 being responsive.</p> <p>5 THE WITNESS: I'm telling</p> <p>6 you what that -- what that answer</p> <p>7 is.</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. If that's responsive, okay.</p> <p>10 A. Okay. So in that context,</p> <p>11 we would have gone over the current --</p> <p>12 the current available choices, we would</p> <p>13 talk, of course, first, about what was</p> <p>14 established and what was commonplace and,</p> <p>15 certainly, what my experience had been.</p> <p>16 We would talk about the</p> <p>17 newer procedure, the preliminary</p> <p>18 experience, the theoretical benefits that</p> <p>19 might come from the newer procedure.</p> <p>20 And I would have been very</p> <p>21 specific with them, as far as what my</p> <p>22 specific experience was, i.e., this is</p> <p>23 the third one I've done, this is the</p> <p>24 fifth one I've done.</p>

29 (Pages 110 to 113)

Marc Toggia, M.D.

<p style="text-align: right;">Page 114</p> <p>1 And also within that</p> <p>2 context, we would have said, thus far in</p> <p>3 this experience, we have seen the</p> <p>4 following outcomes.</p> <p>5 Q. What risks did you tell the</p> <p>6 patient were associated with the TVT --</p> <p>7 A. Sure. I'm sorry.</p> <p>8 Q. -- device when you counseled</p> <p>9 her?</p> <p>10 A. Sure. It's the same</p> <p>11 elemental risks. We would have talked</p> <p>12 about the risks of voiding dysfunction,</p> <p>13 the risk of possible injury to the</p> <p>14 vagina, to the bladder, to blood vessels</p> <p>15 or nerves. The theoretical risk as it</p> <p>16 relates to infection. Any risk that</p> <p>17 might be unique to the placement of -- of</p> <p>18 mesh material.</p> <p>19 It's the same -- it's the</p> <p>20 same discussion that we had with all of</p> <p>21 the procedures that we do.</p> <p>22 Q. What were the risks that you</p> <p>23 would have told your patient that are</p> <p>24 unique to the mesh material?</p>	<p style="text-align: right;">Page 116</p> <p>1 Q. Is it only the difference in</p> <p>2 the material that is exposed in the</p> <p>3 vagina, not the actual fact that TVT can</p> <p>4 become exposed in the vagina?</p> <p>5 A. Well, I think -- I think,</p> <p>6 you know, again, it's -- what we always</p> <p>7 do is we will compare one procedure to</p> <p>8 the next procedure.</p> <p>9 So, for example, you know, a</p> <p>10 Burch procedure is done with a</p> <p>11 laparotomy, okay? There are certain</p> <p>12 risks that are more common with a</p> <p>13 laparotomy, wound infection, wound</p> <p>14 breakdown, bleeding.</p> <p>15 There may be other risks</p> <p>16 that are a little less common with that</p> <p>17 Burch procedure.</p> <p>18 At the time I would say,</p> <p>19 probably bladder injury was a risk that</p> <p>20 we -- in our experience, was maybe a</p> <p>21 little less common, although I think</p> <p>22 Level 1 evidence really suggests that all</p> <p>23 the risks are within in the same</p> <p>24 ballpark.</p>
<p style="text-align: right;">Page 115</p> <p>1 A. In all honesty, and I'm not</p> <p>2 trying to be difficult, I can't tell you</p> <p>3 that the risks are unique. They all</p> <p>4 carry a risk of bladder injury. They all</p> <p>5 carry a risk of urethral injury.</p> <p>6 Autologous fascial slings</p> <p>7 can erode, can have wound disruptions,</p> <p>8 which is a similar risk that, say, a</p> <p>9 midurethral sling could have.</p> <p>10 Q. So is it your opinion that</p> <p>11 there are no risks that are unique to the</p> <p>12 mesh material contained in the TVT</p> <p>13 device?</p> <p>14 A. I mean, obviously, exposure</p> <p>15 of synthetic mesh material, you know, as</p> <p>16 opposed to exposure of permanent suture</p> <p>17 material with the Burch, per se, as</p> <p>18 opposed to, say, exposure of the fascial</p> <p>19 slings.</p> <p>20 Q. So the exposure is the same</p> <p>21 in all three procedures, it's just the</p> <p>22 material that's being exposed is the only</p> <p>23 difference that you can identify?</p> <p>24 A. Say that again, please.</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. Do you get exposure of</p> <p>2 permanent suture in the vagina with a</p> <p>3 Burch procedure?</p> <p>4 A. Yes. It's actually one of</p> <p>5 the more common things that we see.</p> <p>6 Q. Do you get bladder erosion</p> <p>7 with a Burch procedure?</p> <p>8 A. Yes. It's one of the more</p> <p>9 common things that we see.</p> <p>10 Q. How common are bladder</p> <p>11 erosions with a Burch?</p> <p>12 A. Can I refer to one of the</p> <p>13 systematic review studies?</p> <p>14 Q. Sure.</p> <p>15 A. So I was hoping to find a</p> <p>16 more specific -- specific number to give</p> <p>17 you, but I would say, in general, it's</p> <p>18 probably in the 3 to 4 percent range that</p> <p>19 we would see a PROLENE® suture erode into</p> <p>20 the bladder.</p> <p>21 Q. Are PROLENE® sutures used</p> <p>22 commonly for Burch procedures?</p> <p>23 A. Permanent sutures are used</p> <p>24 commonly --</p>

30 (Pages 114 to 117)

Marc Toggia, M.D.

Page 118	Page 120
<p>1 Q. My question is --</p> <p>2 A. -- for Burch procedures.</p> <p>3 Q. -- are PROLENE® suture used</p> <p>4 commonly for Burch procedures?</p> <p>5 A. PROLENE® sutures is -- is a</p> <p>6 common choice of a suture for it, yes.</p> <p>7 Q. Is that what you use if</p> <p>8 you're doing a Burch procedure?</p> <p>9 A. We would either use PROLENE®</p> <p>10 or we would use ETHIBOND. We probably</p> <p>11 use them equally.</p> <p>12 Q. And while you're at it, why</p> <p>13 don't you look for the incidence of</p> <p>14 vaginal exposure of suture with a Burch</p> <p>15 procedure?</p> <p>16 A. To answer that question, I</p> <p>17 think I have to refer to my expert</p> <p>18 report.</p> <p>19 Q. While you're doing that, how</p> <p>20 about urethral exposure --</p> <p>21 A. Counselor, I'm sorry --</p> <p>22 Q. -- with a Burch procedure.</p> <p>23 A. -- being your typical male,</p> <p>24 I don't multitask very well. However, I</p>	<p>1 suture with a Burch procedure?")</p> <p>2 - - -</p> <p>3 THE WITNESS: I recall that</p> <p>4 there was one trial where, I</p> <p>5 believe, approximately 5</p> <p>6 percent -- I might have to find</p> <p>7 the Novara study.</p> <p>8 MS. THOMPSON: Let's just go</p> <p>9 off the record, Greg, if you don't</p> <p>10 mind, while he looks for the</p> <p>11 studies.</p> <p>12 VIDEO TECHNICIAN: We are</p> <p>13 off the record. The time is 3:32</p> <p>14 p.m.</p> <p>15 - - -</p> <p>16 (Whereupon, a discussion off</p> <p>17 the record occurred.)</p> <p>18 - - -</p> <p>19 VIDEO TECHNICIAN: We are</p> <p>20 back on the video record. The</p> <p>21 time is 3:41 p.m.</p> <p>22 THE WITNESS: Thank you. I</p> <p>23 apologize it's taking me so long.</p> <p>24 So the first study that I</p>
Page 119	Page 121
<p>1 guarantee you --</p> <p>2 Q. All right. I will wait.</p> <p>3 A. -- I can do two serial tasks</p> <p>4 very, very, quickly.</p> <p>5 Q. Okay. I'm just trying to</p> <p>6 get you out of here earlier.</p> <p>7 A. Counselor, I am -- I am at</p> <p>8 your disposal. I'm here as long as you</p> <p>9 would like me to be here.</p> <p>10 Q. All right. That's great to</p> <p>11 hear.</p> <p>12 MR. SNELL: She gets seven</p> <p>13 hours on the record.</p> <p>14 THE WITNESS: You've got six</p> <p>15 hours, 15 minutes left.</p> <p>16 Can you read me back the</p> <p>17 question again, please?</p> <p>18 - - -</p> <p>19 (Whereupon, the court</p> <p>20 reporter read the following part</p> <p>21 of the record:</p> <p>22 "Question: And while you're</p> <p>23 at it, why don't you look for the</p> <p>24 incidence of vaginal exposure of</p>	<p>1 want to reference with regard to</p> <p>2 the question of the suture erosion</p> <p>3 to the bladder is going to be the</p> <p>4 Cochrane review. This would be</p> <p>5 the Lapitan and Cody study, 2012</p> <p>6 Cochrane review.</p> <p>7 Data from -- and they're</p> <p>8 referencing the Albo trial.</p> <p>9 Data from this trial showed</p> <p>10 a fivefold higher risk of having</p> <p>11 sutures pass through the bladder</p> <p>12 with open colposuspension compared</p> <p>13 to doing a pubovaginal sling</p> <p>14 procedure; perforation rate, 3</p> <p>15 percent.</p> <p>16 And if you'd like to go off</p> <p>17 the record again, I'm happy to</p> <p>18 find the second paper.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. That's talking about</p> <p>21 intraoperative risk, correct, not</p> <p>22 erosion?</p> <p>23 Dr. Toggia --</p> <p>24 A. Yes? I'm sorry.</p>

31 (Pages 118 to 121)

Marc Toggia, M.D.

Page 122	Page 124
<p>1 Q. -- the passage you just read 2 to me is talking about an intraoperative 3 risk of passing suture through the 4 bladder, correct? 5 A. Sutures passed through the 6 bladder during open colposuspension. 7 Q. That's not referring to 8 erosion into the bladder, is it? 9 A. No, it's not. I'm sorry. 10 So it wasn't suture -- it 11 wasn't suture exposure in the 12 bladder, was that -- was that not 13 the question? 14 Q. The question was bladder 15 erosion of suture with a Burch 16 colposuspension. 17 So you'll agree that the 18 sentence you just read doesn't have 19 anything to do with bladder erosion? 20 A. Counselor, I will agree that 21 the sentence I just read you talked about 22 the passage of suture into the bladder. 23 I'm sorry if I -- 24 Q. And that's not erosion,</p>	<p>1 BY MS. THOMPSON: 2 Q. And what about the risk of 3 suture erosion into the vagina with a 4 Burch? 5 A. I would say it's probably in 6 the -- in the same ballpark. 7 Q. And what about suture 8 erosion into the urethra with a Burch? 9 A. That should really not 10 occur, because the Burch suspension is 11 not placed at the level of the urethra. 12 Q. And it's your testimony -- 13 but, at least as you're sitting here 14 today, you can't give me a reference for 15 those numbers? 16 A. Yes. 17 Q. Yes, you cannot? 18 A. Yes, I cannot give you a 19 reference for those numbers. Yes. 20 Q. Thank you. 21 And is your testimony, then, 22 that there's really no complications that 23 are unique to the -- to a synthetic 24 midurethral sling?</p>
Page 123	Page 125
<p>1 correct? 2 A. I'm sorry if I misunderstood 3 your question. 4 MS. THOMPSON: I guess we'll 5 go off the record again. 6 THE WITNESS: Thank you. 7 VIDEO TECHNICIAN: We are 8 off the record. The time is 3:44 9 p.m. 10 - - - 11 (Whereupon, a discussion off 12 the record occurred.) 13 - - - 14 VIDEO TECHNICIAN: We are 15 back on the record. 16 THE WITNESS: Thank you. So 17 with regard to the question of the 18 rate of suture erosion into the 19 bladder, it's my general 20 recollection that there's about a 21 3 to 5 percent risk of suture 22 erosion with the traditional Burch 23 procedure when performed with 24 PROLENE® sutures.</p>	<p>1 MR. SNELL: Objection. 2 Asked and answered. 3 THE WITNESS: Each procedure 4 has risks. The majority of those 5 risks, I would say are elemental, 6 are common to the group. However, 7 each procedures do have risks that 8 are more common, perhaps, and 9 possibly could be unique. 10 For example, with the 11 poly-tetrafluoride sling, there 12 was -- or the Ob Tape sling -- 13 BY MS. THOMPSON: 14 Q. Let me clarify my question 15 and just limit it to synthetic 16 polypropylene slings. 17 A. Okay. Thank you. 18 So with -- with reference to 19 the TVT Type I polypropylene sling -- I'm 20 sorry, but I can't think of a risk that's 21 unique to that -- to that compared to the 22 other procedures that we do. 23 Q. And you'll agree with me 24 that, in terms of significance, the</p>

32 (Pages 122 to 125)

Marc Toggia, M.D.

Page 126	Page 128
<p>1 severity of a complication is important, 2 correct? 3 A. I'm not sure that I 4 understand your question. 5 Q. When you're considering 6 risks associated with a procedure, the 7 severity of that complication is 8 important to you as a physician, correct? 9 A. Can you tell me what you 10 mean by "severity"? 11 Q. Well, there are minor 12 complications and there are severe 13 complications, right? 14 A. But one person's minor 15 complication is a severe complication, 16 and vice versa. 17 Could you be -- 18 Q. Well, there are actually 19 some definitions of the severity of 20 complications. 21 But you'll agree with me 22 that -- are you just really telling me -- 23 A. No, counselor -- 24 Q. -- that you don't understand</p>	<p>1 A. I'm sorry. I understand you 2 now. 3 Q. Okay. 4 A. Yes. 5 Q. All right. 6 A. So, for example, urinary 7 tract infection is oftentimes cited as a 8 complication. One can argue that a 9 urinary tract infection would be a less 10 severe type of a complication. 11 Q. But a urinary tract 12 infection with sepsis and intensive care 13 could be a serious complication? 14 A. That's a good point, 15 counselor. 16 Q. Thank you. 17 MR. SNELL: Can we take a 18 break whenever you get right a 19 stopping point? Because I need to 20 use the restroom. 21 MS. THOMPSON: Maybe five 22 minutes. 23 MR. SNELL: That's fine. 24 BY MS. THOMPSON:</p>
Page 127	Page 129
<p>1 what I mean by the severity of a 2 complication is important? 3 A. I'm just not sure of the 4 context. 5 So, first of all, I will 6 agree with you that there are less severe 7 complications and there are more severe 8 complications with each of these 9 anti-incontinence procedures. 10 Q. That was all I'm asking. 11 A. I'm sorry. 12 Q. And I wasn't even specific 13 to -- 14 A. Okay. 15 Q. -- to a device. 16 I was just saying, there are 17 minor complications and severe 18 complications, right? 19 A. Yes. 20 Q. And that makes a difference 21 whether you're talking about a rate of 22 minor complications or you're rating -- 23 talking about a rate of severe 24 complications?</p>	<p>1 Q. Now, when we started this 2 line of questioning, it's been a while, 3 but I think we were talking about what 4 you told your patients in 1999 -- 5 A. Yes. 6 Q. -- when you first started -- 7 A. I'm sorry, yes. 8 Q. -- using the TVT. 9 I have a little bit 10 different question and that is now, in 11 2015, when you are using a retropubic TVT 12 device, are there any additional risks or 13 complications that you discuss with your 14 patients, as opposed to what you did in 15 the early years of using the device? 16 A. Well, now that I'm 17 years 17 into this experience and now that I've 18 done, let's say, well over 2,000 cases, 19 again, I like to talk to my patients 20 about things that might go wrong during 21 the procedure, things that possibly could 22 complicate their postoperative course, 23 things that might occur during the life 24 of that procedure.</p>

33 (Pages 126 to 129)

Marc Toggia, M.D.

<p style="text-align: right;">Page 130</p> <p>1 So to speak backwards, what 2 we typically tell our patients these days 3 is that, you know, over the ten-year 4 period, subsequent to, say, having a 5 midurethral sling -- and when I say 6 "midurethral sling," I am referring 7 specifically to the TVT, since that's 8 what I perform, there's about a 3 9 and-a-half percent risk of having to 10 return to the OR for something; that 11 might include failure, that could include 12 difficulty voiding, et cetera. 13 Overall, the risk that we 14 talk to people about, in our hands, are 15 sort of the risk of bladder injuries, 16 about 1 percent; our mesh exposure rate 17 is under 1 percent; our risk of voiding 18 dysfunction is well under 1 percent; our 19 rate of infection has been zero percent 20 over -- over the 17-year experience; the 21 rates of urethral injury, well under 1 22 percent. 23 And I make it a point of 24 saying, look, just because something</p>	<p style="text-align: right;">Page 132</p> <p>1 or prevalence. I'm asking how many are 2 reported? 3 A. I don't know. I would -- I 4 would venture -- I don't know. 5 Q. Are you aware of any -- 6 A. I -- 7 Q. -- reported? 8 A. I'm aware of, I'm going to 9 say, five to seven deaths. 10 Q. Reported in the literature, 11 is my question? 12 A. Oh, reported in the 13 literature -- I don't know how many have 14 been reported in the literature. 15 Q. Are you aware of any deaths 16 reported in the literature from the TVT 17 device? 18 A. You know, when I -- 19 Q. The question is, are you 20 aware of any? 21 A. I'm just trying to explain 22 to you, if I'm aware of five to seven I 23 wouldn't be -- 24 Q. I'm not asking you how many</p>
<p style="text-align: right;">Page 131</p> <p>1 occurs very infrequently, doesn't 2 necessarily mean that when it does occur 3 it's not a significant complication. 4 Q. Are synthetic sling 5 complications underreported in the 6 literature, in your opinion? 7 A. Absolutely not. Again, we 8 have -- we have more than 20 -- excuse 9 me, we have at least, you know, eight to 10 ten long-term registry studies that have 11 followed people for at least five years. 12 Some studies have gone out to ten years. 13 And these are high quality, high level of 14 evidence, of scientific papers. 15 And I would say, you know, 16 ballpark figure, long-term complications 17 are all sub 3 percent. 18 Q. How many deaths are reported 19 in the literature from the TVT retropubic 20 device? 21 A. And, again, I don't think 22 that you can derive incidence or 23 prevalence because, you know -- 24 Q. I'm not asking for incidence</p>	<p style="text-align: right;">Page 133</p> <p>1 you think have occurred -- 2 A. Right. 3 Q. -- I'm asking you how many 4 have been reported in the literature? 5 A. In my reading of the 6 literature, I'm saying that I am aware of 7 about five to seven. I'm just saying 8 that I cannot produce to you what -- in 9 what form or publication they would have 10 been. 11 Q. And how many do you think 12 have actually occurred? 13 A. I don't know, counselor. 14 Q. So you think there are five 15 to seven deaths reported in the 16 literature from TVT? 17 A. That's the best of my 18 recollection. But I will tell you that 19 I'm not aware of any personally. 20 Q. Do you tell your patients 21 that polypropylene degrades in the human 22 body? 23 A. There is no high-quality 24 evidence that suggests that polypropylene</p>

34 (Pages 130 to 133)

Marc Toggia, M.D.

Page 134	Page 136
<p>1 degrades in the body.</p> <p>2 Q. What does degradation mean</p> <p>3 to you?</p> <p>4 A. Well, again, and I looked</p> <p>5 this up. It just -- it depends. And the</p> <p>6 definition varies.</p> <p>7 Degradation is -- to me,</p> <p>8 means a loss of structural integrity, a</p> <p>9 loss of function.</p> <p>10 You can certainly degrade</p> <p>11 one's morality, that's a different</p> <p>12 mention, that's obviously not applicable</p> <p>13 within the setting of the mesh.</p> <p>14 Q. Okay. And it's your opinion</p> <p>15 that there's no high-quality study that</p> <p>16 shows -- that mesh degrades?</p> <p>17 A. I'm quite certain that there</p> <p>18 is no high-quality studies that would</p> <p>19 suggest that the mesh degrades. It is</p> <p>20 certainly inconsistent with the body of</p> <p>21 Level 1 evidence and the long-term</p> <p>22 registration studies.</p> <p>23 Q. Is there high-quality</p> <p>24 evidence, in your opinion, that states</p>	<p>1 structural composition of the</p> <p>2 polypropylene.</p> <p>3 MR. SNELL: I'm going to</p> <p>4 object. That misstates. He said</p> <p>5 structural -- well, the record</p> <p>6 will be clear what he said. And I</p> <p>7 think he was responsive with</p> <p>8 regard to how he defines</p> <p>9 degradation.</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. Okay. I'm going to -- I'm</p> <p>12 going to define degradation in the</p> <p>13 chemical sense, and that is a change in</p> <p>14 the chemical structure of the compound.</p> <p>15 A. Okay.</p> <p>16 Q. Are there any studies in the</p> <p>17 literature that tell you that that does</p> <p>18 not happen with the TVT mesh when placed</p> <p>19 in a woman's body?</p> <p>20 A. Can I ask you to restate</p> <p>21 that without the double negative, please?</p> <p>22 Q. Well, you told me there are</p> <p>23 no high-quality studies that state that</p> <p>24 it degrades. I don't know how to do that</p>
Page 135	Page 137
<p>1 that mesh does not degrade?</p> <p>2 A. Well, I don't know how we</p> <p>3 would know that, counselor, because we</p> <p>4 don't routinely explant mesh that is</p> <p>5 behaving properly in the body.</p> <p>6 Q. Does mesh that's not</p> <p>7 behaving properly in the body degrade?</p> <p>8 A. Again, I'm not aware of any</p> <p>9 high-quality data. I can tell you</p> <p>10 that -- the data is very, very clear and</p> <p>11 very reassuring that there are no</p> <p>12 clinical concerns that that phenomenon</p> <p>13 exists.</p> <p>14 Q. That's not my question. I'm</p> <p>15 not talking clinically.</p> <p>16 A. Yes.</p> <p>17 Q. I'm talking about, and I</p> <p>18 would --</p> <p>19 A. Degrading in the body is a</p> <p>20 clinically-based question.</p> <p>21 Q. No. I'm talking about</p> <p>22 degradation, not clinical.</p> <p>23 A. Okay.</p> <p>24 Q. But you mentioned the</p>	<p>1 without the negative.</p> <p>2 Are there any studies that</p> <p>3 show you that it does not degrade?</p> <p>4 A. The study by Falconer, which</p> <p>5 I believe was published in 2001, where</p> <p>6 they did, in fact, go back and take site</p> <p>7 specific biopsies showed no degradation</p> <p>8 in the material.</p> <p>9 Q. Now, were they looking at</p> <p>10 that from a chemical composition</p> <p>11 standpoint?</p> <p>12 A. Again, if you would like to</p> <p>13 give me a minute to locate that study.</p> <p>14 MS. THOMPSON: Okay. We'll</p> <p>15 go off the record.</p> <p>16 VIDEO TECHNICIAN: We are</p> <p>17 off the record. The time is 3:58</p> <p>18 p.m.</p> <p>19 - - -</p> <p>20 (Whereupon, a discussion off</p> <p>21 the record occurred.)</p> <p>22 - - -</p> <p>23 VIDEO TECHNICIAN: We are</p> <p>24 back on the video record.</p>

35 (Pages 134 to 137)

Marc Toggia, M.D.

Page 138	Page 140
<p>1 THE WITNESS: Read me the 2 question one more time, please? 3 - - - 4 (Whereupon, the court 5 reporter read the following part 6 of the record: 7 "Question: Now, were they 8 looking at that from a chemical 9 composition standpoint?") 10 - - - 11 THE WITNESS: So, no. The 12 Falconer study was looking at it 13 from a histologic standpoint. I'm 14 not aware of any concerns that 15 there might be degradation that 16 would prompt one to do those kinds 17 of studies. 18 BY MS. THOMPSON: 19 Q. And that study also was 20 biopsying the tissue around the mesh 21 product, not the mesh itself, correct? 22 A. You are correct, counselor. 23 Q. So you're not aware of any 24 studies, then, that demonstrates that</p>	<p>1 chemical degradation does not occur with 2 polypropylene mesh implanted in the body? 3 A. I think that the long-term 4 registry trials and the significant lack 5 of chronic problems suggests that there 6 is no chemical degradation of the 7 material. 8 I'm also -- I'm a little 9 bit -- what does it matter if the 10 material degrades if the person is still 11 continent? You know, it's not that 12 are -- we're suspending somebody from a 13 bridge from this material and that loss 14 of the material would compromise that 15 person's position. 16 The procedure is designed to 17 reestablish urethral stability, and it 18 does so effectively in studies that have 19 gone up to 17 years. 20 Q. So is it your opinion that 21 degradation -- chemical degradation of 22 the material doesn't matter if the woman 23 is still continent? 24 A. Well, and, again, I'm</p>
Page 139	Page 141
<p>1 polypropylene mesh does -- or TVT mesh 2 does not degrade in the female body? 3 MR. SNELL: Objection. 4 Asked and answered. 5 MS. THOMPSON: Well, he said 6 he would look and he found 7 Falconer, which doesn't apply, so 8 I'm asking if he has any others. 9 MR. SNELL: I'm going to 10 object. That's also vague. You 11 asked him specifically, in the 12 last question, about chemical 13 degradation. And now you said 14 degradation. He already said he 15 doesn't think degradation occurs, 16 and he's told you all the reasons 17 why. 18 MS. THOMPSON: All right. 19 Fair enough. I'll ask it -- I'll 20 ask again with chemical 21 degradation. 22 BY MS. THOMPSON: 23 Q. Are you aware of any 24 studies, then, that demonstrate that</p>	<p>1 certainly not trying to be difficult, but 2 I'm not certain what you mean by 3 "chemical degradation," what 4 specifically, what we're looking at, 5 we're changing in, we're talking about 6 isomeric change in the compound? We're 7 talking about racemic change in the 8 compound? We're talking about 9 nephelation of the compound? What -- 10 what specifically is implied with the 11 term "chemical degradation"? 12 Q. You're not a chemist, right? 13 A. I have a degree in 14 biochemistry. I have done chemical 15 research. 16 Q. But you don't consider 17 yourself a chemist? 18 MR. SNELL: Objection. 19 THE WITNESS: I think I just 20 told you what my -- 21 BY MS. THOMPSON: 22 Q. So you are a chemist? 23 A. What's that? I -- 24 Q. You do consider yourself an</p>

36 (Pages 138 to 141)

Marc Toggia, M.D.

Page 142	Page 144
<p>1 expert in chemistry?</p> <p>2 A. Those are different</p> <p>3 questions.</p> <p>4 Q. Do you consider yourself an</p> <p>5 expert in chemistry?</p> <p>6 A. I would consider myself an</p> <p>7 expert in chemistry, yes.</p> <p>8 Q. And -- but you're not</p> <p>9 familiar -- are you familiar with the</p> <p>10 term "oxidation"?</p> <p>11 A. Of course.</p> <p>12 Q. Are you familiar with the</p> <p>13 term "oxidative degradation"?</p> <p>14 A. Yes.</p> <p>15 Q. Let's just use oxidative</p> <p>16 degradation, then, maybe we can --</p> <p>17 A. Fair enough.</p> <p>18 Q. -- get on the same page</p> <p>19 here.</p> <p>20 A. Sure.</p> <p>21 Q. Are you aware of any studies</p> <p>22 that show that oxidative degradation does</p> <p>23 not occur with polypropylene mesh placed</p> <p>24 in the body?</p>	<p>1 mesh, within the context of the TVT</p> <p>2 device and its intended use to treat</p> <p>3 stress incontinence in women, which was</p> <p>4 the subject that I was asked to research</p> <p>5 and form an opinion, undergoes oxidative</p> <p>6 degradation.</p> <p>7 Q. Are you a materials expert?</p> <p>8 A. I certainly am a materials</p> <p>9 expert, yes. At least --</p> <p>10 Q. Are you a polymer expert?</p> <p>11 A. I have a better than</p> <p>12 average, and some would consider to be an</p> <p>13 expert understanding, of polymer medicine</p> <p>14 as it relates to my subspecialty field,</p> <p>15 yes.</p> <p>16 Q. Is it your opinion -- well,</p> <p>17 let me ask you this: What additives go</p> <p>18 into the mesh that the TVT is comprised</p> <p>19 of?</p> <p>20 A. Can you be more specific?</p> <p>21 Q. What additives are added to</p> <p>22 the polypropylene resin that makes up the</p> <p>23 TVT?</p> <p>24 A. I mean, there's an enormous</p>
Page 143	Page 145
<p>1 A. There are no high-quality</p> <p>2 evidence studies that suggest that it</p> <p>3 does occur. Therefore, my inference</p> <p>4 would be that it does not occur.</p> <p>5 Q. What does oxidative</p> <p>6 degradation mean to you?</p> <p>7 A. Oxidative degradation is the</p> <p>8 process in which oxygen comes in and will</p> <p>9 alter the composition; so, you know,</p> <p>10 you've got nitrous oxide it becomes</p> <p>11 nitric oxide.</p> <p>12 Q. What happens when</p> <p>13 polypropylene undergoes oxidative</p> <p>14 degradation?</p> <p>15 MR. SNELL: Objection. It</p> <p>16 lacks foundation. He's told you</p> <p>17 he doesn't believe it does.</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. So is it your opinion that</p> <p>20 polypropylene does not undergo oxidative</p> <p>21 degradation in vitro or in vivo?</p> <p>22 A. I'm speaking in vivo; I'm</p> <p>23 not aware of any high-quality evidence</p> <p>24 that would suggest that polypropylene</p>	<p>1 amount --</p> <p>2 Q. If you don't know, it's</p> <p>3 fine. Just say you don't know.</p> <p>4 What additives go into the</p> <p>5 mesh -- to the resin that forms the TVT</p> <p>6 mesh?</p> <p>7 A. I'm not sure I know what</p> <p>8 you're referring to, in terms of adding</p> <p>9 oxygen goes into it.</p> <p>10 Q. Is the polypropylene that's</p> <p>11 used in the TVT mesh pure polypropylene?</p> <p>12 A. Well, no. Polypropylene</p> <p>13 itself is not a pure molecule. I mean,</p> <p>14 there are --</p> <p>15 Q. What is added to the</p> <p>16 polypropylene or is nothing added or do</p> <p>17 you not know?</p> <p>18 A. I can't tell you off the top</p> <p>19 of my head all of the different compounds</p> <p>20 that would go into the -- you know, the</p> <p>21 creation and the extrusion of</p> <p>22 polypropylene.</p> <p>23 Q. Did you ever ask anyone at</p> <p>24 Ethicon what was in the polypropylene?</p>

37 (Pages 142 to 145)

Marc Toggia, M.D.

Page 146	Page 148
<p>1 A. I did not ask anybody at</p> <p>2 Ethicon what was in polypropylene.</p> <p>3 But that shouldn't imply</p> <p>4 that I did not read about polypropylene</p> <p>5 mesh or the base PROLENE® material.</p> <p>6 These are materials that we have used</p> <p>7 extensively in the last 40 to 50 years in</p> <p>8 the area of surgery.</p> <p>9 Q. Did Ethicon tell you that</p> <p>10 its own studies on PROLENE® suture shows</p> <p>11 that it degrades?</p> <p>12 MR. SNELL: Objection.</p> <p>13 Misstates. Lacks foundation.</p> <p>14 THE WITNESS: I would not</p> <p>15 rely upon Ethicon to tell me such</p> <p>16 things.</p> <p>17 And, again, this is within</p> <p>18 the context of the TVT design, I'm</p> <p>19 not aware of -- you know, the</p> <p>20 animal studies really are not</p> <p>21 relevant. We have Level 1</p> <p>22 evidence to support the long-term</p> <p>23 safety of these things --</p> <p>24 BY MS. THOMPSON:</p>	<p>1 MR. SNELL: Objection.</p> <p>2 Lacks foundation. Misstates</p> <p>3 evidence.</p> <p>4 THE WITNESS: No, it is not.</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. It's not something that you</p> <p>7 would want to know?</p> <p>8 A. I would not want to know it</p> <p>9 from Ethicon, no.</p> <p>10 Q. Who would you know it from?</p> <p>11 A. Would I know what from?</p> <p>12 Q. Who is going to tell you</p> <p>13 that Ethicon mesh degrades if it's not</p> <p>14 Ethicon?</p> <p>15 MR. SNELL: Objection.</p> <p>16 Hypothetical. Calls for</p> <p>17 speculation.</p> <p>18 MS. THOMPSON: Well, he</p> <p>19 brought it up. He didn't want to</p> <p>20 hear it from Ethicon.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. I'm asking you, who else</p> <p>23 would you want to hear it from?</p> <p>24 MR. SNELL: You asked him</p>
Page 147	Page 149
<p>1 Q. I'm not talking about -- if</p> <p>2 we can get away from the long-term</p> <p>3 safety. I'm not discussing the long-term</p> <p>4 safety. I'm discussing the material</p> <p>5 itself.</p> <p>6 A. Yes.</p> <p>7 Q. If Ethicon has information</p> <p>8 that the material degrades in the human</p> <p>9 body, is that something that you, as a</p> <p>10 doctor, would want to know about?</p> <p>11 MR. SNELL: Objection.</p> <p>12 Lacks foundation.</p> <p>13 Go ahead.</p> <p>14 THE WITNESS: I would not be</p> <p>15 dependent upon Ethicon --</p> <p>16 BY MS. THOMPSON:</p> <p>17 Q. I didn't ask you --</p> <p>18 A. -- for that information.</p> <p>19 Q. -- if you depended on it.</p> <p>20 Is that something that you</p> <p>21 would like to know, if Ethicon has</p> <p>22 information that their product degrades,</p> <p>23 is that something you would want to know,</p> <p>24 as a physician?</p>	<p>1 the question. He's already told</p> <p>2 you he doesn't think it degrades.</p> <p>3 I don't know -- I don't understand</p> <p>4 what you're doing.</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. I'm saying if Ethicon has</p> <p>7 knowledge that it degrades, is that</p> <p>8 something you want to know?</p> <p>9 MR. SNELL: He's already --</p> <p>10 objection. Asked and answered</p> <p>11 three times.</p> <p>12 MS. THOMPSON: Okay. I</p> <p>13 thought maybe he would change his</p> <p>14 opinion on that.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Would patients want to know</p> <p>17 if the material, the plastic that they're</p> <p>18 putting in their bodies, degrades?</p> <p>19 MR. SNELL: Objection.</p> <p>20 Calls for speculation.</p> <p>21 THE WITNESS: I think the</p> <p>22 only thing the patients would want</p> <p>23 to know is whether or not the</p> <p>24 procedure worked long-term for</p>

38 (Pages 146 to 149)

Marc Toggia, M.D.

Page 150	Page 152
<p>1 them.</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. Okay. So, to you, if the</p> <p>4 procedure works, it doesn't really matter</p> <p>5 whether that material degrades or not?</p> <p>6 A. Absolutely.</p> <p>7 Q. All right.</p> <p>8 A. It does not matter to me.</p> <p>9 Q. Thank you.</p> <p>10 MS. THOMPSON: We'll take a</p> <p>11 break.</p> <p>12 VIDEO TECHNICIAN: We are</p> <p>13 off the record. The time is 4:11</p> <p>14 p.m.</p> <p>15 - - -</p> <p>16 (Whereupon, a brief recess</p> <p>17 was taken.)</p> <p>18 - - -</p> <p>19 VIDEO TECHNICIAN: This</p> <p>20 marks the beginning of Video</p> <p>21 Number 3. We are back on the</p> <p>22 record. The time is 4:38 p.m.</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Dr. Toggia, when we went on</p>	<p>1 instance in which polypropylene mesh</p> <p>2 caused a chronic foreign body reaction.</p> <p>3 I feel that that is very</p> <p>4 consistent with the long-term registries</p> <p>5 trials --</p> <p>6 Q. Okay.</p> <p>7 A. -- that it focused on the</p> <p>8 safety and looked specifically for that</p> <p>9 kind of problem.</p> <p>10 Q. Do you -- if Ethicon had</p> <p>11 information that the mesh used in the TVT</p> <p>12 creates a chronic ongoing foreign body</p> <p>13 reaction, is that information that you</p> <p>14 would want to know?</p> <p>15 MR. SNELL: Objection.</p> <p>16 Lacks foundation.</p> <p>17 THE WITNESS: As a general</p> <p>18 rule of thumb, I am not dependent</p> <p>19 upon Ethicon to provide me with</p> <p>20 any such information.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Is it information that your</p> <p>23 patients would want to know?</p> <p>24 A. I honestly don't believe</p>
Page 151	Page 153
<p>1 our break, I was asking you about what</p> <p>2 you tell your patients now about</p> <p>3 polypropylene mesh and the TVT device.</p> <p>4 Do you remember that?</p> <p>5 A. Yes.</p> <p>6 Q. Do you tell your patients</p> <p>7 that polypropylene mesh creates a chronic</p> <p>8 foreign body reaction in the body?</p> <p>9 A. I don't tell them that,</p> <p>10 because there is no evidence that it</p> <p>11 causes a chronic foreign body -- counsel,</p> <p>12 I'm sorry, it's staring right in front of</p> <p>13 me here. I did address your question</p> <p>14 about oxidation --</p> <p>15 Q. I didn't ask you any other</p> <p>16 questions, so Mr. Snell can ask you about</p> <p>17 that later.</p> <p>18 A. Okay. Thank you.</p> <p>19 Q. So it's your opinion that</p> <p>20 polypropylene mesh does not create a</p> <p>21 foreign body reaction in the body?</p> <p>22 A. My experience, in using</p> <p>23 polypropylene over the last 17 years, I</p> <p>24 have never seen an incidence -- an</p>	<p>1 that they would care to know.</p> <p>2 Q. Do you tell your patients</p> <p>3 that polypropylene mesh shrinks up to 30</p> <p>4 percent?</p> <p>5 A. I believe -- well, the</p> <p>6 discussion is that -- and, again, within</p> <p>7 the context of the TVT sling, as it was</p> <p>8 used for stress incontinence, I don't</p> <p>9 believe that would -- that small amount</p> <p>10 of lightweight macroporous material, that</p> <p>11 clinically there is a relevant amount of</p> <p>12 shrinkage.</p> <p>13 In the context of other</p> <p>14 discussions with other base procedures,</p> <p>15 there is a discussion that has to do with</p> <p>16 changes in the mesh, as you stated, but</p> <p>17 not for TVT sling, no.</p> <p>18 Q. So the answer is, no, that</p> <p>19 you don't tell your patients about</p> <p>20 shrinkage of the TVT sling?</p> <p>21 MR. SNELL: Objection.</p> <p>22 Misstates.</p> <p>23 MS. THOMPSON: Will you stop</p> <p>24 the speaking objections? Just say</p>

39 (Pages 150 to 153)

Marc Toggia, M.D.

Page 154	Page 156
<p>1 object, and without --</p> <p>2 MR. SNELL: No. No. I'm</p> <p>3 allowed to state the objection to</p> <p>4 form. That is a form objection.</p> <p>5 Misstates.</p> <p>6 MS. THOMPSON: Objection to</p> <p>7 form. You can't go into all the</p> <p>8 other stuff that you've been</p> <p>9 doing.</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. Go ahead and answer the</p> <p>12 question, Dr. Toggia.</p> <p>13 A. It's my -- it's my expert</p> <p>14 opinion that the TVT mesh does not, in</p> <p>15 fact, shrink in vivo.</p> <p>16 Q. Do you tell your patients</p> <p>17 about the possibility of chronic pain</p> <p>18 syndromes?</p> <p>19 MR. SNELL: Hold on.</p> <p>20 Objection. Form.</p> <p>21 MS. THOMPSON: You can</p> <p>22 answer, though.</p> <p>23 MR. SNELL: Go ahead.</p> <p>24 THE WITNESS: In the 17</p>	<p>1 evaluations that we'll see them for. The</p> <p>2 first one is always within the first four</p> <p>3 months or so -- excuse me, within the</p> <p>4 first four weeks or so.</p> <p>5 Usually, there's a second</p> <p>6 follow-up within three months or so.</p> <p>7 Subsequent to that, it may</p> <p>8 be six or 12 months.</p> <p>9 Again, you know, stress</p> <p>10 incontinence, unfortunately, rarely</p> <p>11 happens in isolation. These are patients</p> <p>12 that have chronic pelvic floor disorders.</p> <p>13 I would say, in a large number of our</p> <p>14 cases, we continue to see those patients</p> <p>15 annually.</p> <p>16 Those patients that, at some</p> <p>17 point -- or, let's say, as you said</p> <p>18 earlier, were cured of their problem are</p> <p>19 told that they are welcome to come back</p> <p>20 with any concern that they might have.</p> <p>21 Q. What is your rate of</p> <p>22 follow-up with patients who receive a TVT</p> <p>23 sling.</p> <p>24 A. Our rate of follow-up is</p>
Page 155	Page 157
<p>1 years that I have been implanting</p> <p>2 the TVT mesh for the indication of</p> <p>3 stress incontinence, in over 2,500</p> <p>4 patients, let's say, I have never</p> <p>5 once seen chronic pain syndrome</p> <p>6 arise from the retropubic TVT</p> <p>7 sling that we are discussing</p> <p>8 today.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. So you're saying you have</p> <p>11 never, not one single patient, have you</p> <p>12 seen a chronic pain syndrome related to</p> <p>13 the retropubic TVT?</p> <p>14 A. That's what I said.</p> <p>15 Q. And how would you know?</p> <p>16 A. We -- now, my practice is in</p> <p>17 suburban Philadelphia, we have very high</p> <p>18 rates of follow-up. Patients are seen on</p> <p>19 a regular basis. They are -- they will</p> <p>20 contact us with problems. We tend to see</p> <p>21 the problems.</p> <p>22 Q. When do you see your patient</p> <p>23 for a postoperative checkup after a TVT?</p> <p>24 A. Well, there are a series of</p>	<p>1 above the 90 percentile.</p> <p>2 Q. What do you mean by "90</p> <p>3 percentile"?</p> <p>4 A. Excuse me, I apologize. 90</p> <p>5 percent or higher.</p> <p>6 Q. And how is that determined?</p> <p>7 A. Because we have records and</p> <p>8 we follow-up with patients after surgery</p> <p>9 to make sure that they come in for their</p> <p>10 scheduled visits.</p> <p>11 And the ones that don't,</p> <p>12 that fall through, typically are</p> <p>13 contacted.</p> <p>14 Q. At what point?</p> <p>15 A. As I mentioned to you, I</p> <p>16 think I described for you the parameters</p> <p>17 for our follow-up.</p> <p>18 So if somebody -- I mean,</p> <p>19 obviously, there are -- you know, people</p> <p>20 go on vacation, have to take care of a</p> <p>21 loved one. So if they are not seen, say,</p> <p>22 at that four-week mark, they're asked to</p> <p>23 follow up with -- they are scheduled for</p> <p>24 an appointment, say, within that</p>

40 (Pages 154 to 157)

Marc Toglia, M.D.

Page 158	Page 160
<p>1 three-month period of time.</p> <p>2 Q. So if I requested</p> <p>3 documentation of your rate of follow-up</p> <p>4 on your patients who receive TVT devices,</p> <p>5 could you provide that to me?</p> <p>6 MR. SNELL: Objection. We</p> <p>7 are not producing any of his</p> <p>8 clinical records or charts, nor</p> <p>9 have you produced any such thing</p> <p>10 like that.</p> <p>11 Your experts --</p> <p>12 MS. THOMPSON: I didn't ask</p> <p>13 for clinical records and charts.</p> <p>14 I asked him, could he provide it.</p> <p>15 And you can answer the</p> <p>16 question.</p> <p>17 And that's a speaking</p> <p>18 objection.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Go ahead, Dr. Toglia.</p> <p>21 A. I personally --</p> <p>22 MR. SNELL: Actually, I'm</p> <p>23 objecting and saying that will not</p> <p>24 be produced. I'm putting that on</p>	<p>1 Go ahead and finish telling</p> <p>2 her.</p> <p>3 THE WITNESS: Counselor, you</p> <p>4 asked --</p> <p>5 MS. THOMPSON: And that's a</p> <p>6 speaking objection.</p> <p>7 THE WITNESS: Counselor, you</p> <p>8 asked me the type of follow-up we</p> <p>9 have and you specifically asked me</p> <p>10 what do we do in the situation if</p> <p>11 someone were to not follow up.</p> <p>12 And I gave you a very</p> <p>13 specific answer that the patients</p> <p>14 are contacted. And, oftentimes,</p> <p>15 they are contacted by myself.</p> <p>16 BY MS. THOMPSON:</p> <p>17 Q. Dr. Toglia, if you would try</p> <p>18 to listen closely to my question, because</p> <p>19 a lot of your answers, I'm -- I'm sorry</p> <p>20 I'm losing my patience, are not the</p> <p>21 answer to the question that I'm asking.</p> <p>22 So if you just try to listen, we'll get</p> <p>23 out a lot quicker, okay?</p> <p>24 A. I don't always understand</p>
Page 159	Page 161
<p>1 the record.</p> <p>2 MS. THOMPSON: I didn't ask</p> <p>3 for production, did I?</p> <p>4 BY MS. THOMPSON:</p> <p>5 Q. Go ahead and answer, Dr.</p> <p>6 Toglia.</p> <p>7 Could you provide it if I</p> <p>8 ask for it?</p> <p>9 A. I would not provide that.</p> <p>10 Q. That wasn't my question.</p> <p>11 Could it be provided?</p> <p>12 You've already testified that you don't</p> <p>13 even know how to keep track of what</p> <p>14 procedures are done --</p> <p>15 A. I disagree with you,</p> <p>16 counselor. I told you -- I gave you</p> <p>17 specific examples --</p> <p>18 Q. The record speaks for</p> <p>19 itself.</p> <p>20 A. -- of how --</p> <p>21 MR. SNELL: Don't cut him</p> <p>22 off. He's telling you -- because</p> <p>23 you just -- you just threw an</p> <p>24 insult at him.</p>	<p>1 what it is that you're asking.</p> <p>2 Q. Let's make it clear from</p> <p>3 this point forward, if you don't</p> <p>4 understand my question, will you ask me</p> <p>5 to repeat it or rephrase, but not answer</p> <p>6 a different question, okay?</p> <p>7 MR. SNELL: And I'm going to</p> <p>8 object to counsel's statement. I</p> <p>9 think the witness has been</p> <p>10 responsive. She just doesn't like</p> <p>11 his answers. That's my position.</p> <p>12 MS. THOMPSON: I'm loving</p> <p>13 his answers. That's fine.</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. My question is, I asked you</p> <p>16 about your rate of follow-up --</p> <p>17 A. Correct.</p> <p>18 Q. -- and you said it was above</p> <p>19 the 90 percent mark.</p> <p>20 And I'm asking you, is that</p> <p>21 something that could be provided, if I</p> <p>22 requested it?</p> <p>23 A. It is probably something</p> <p>24 that could be provided.</p>

41 (Pages 158 to 161)

Marc Toggia, M.D.

Page 162	Page 164
<p>1 Q. And what records would you</p> <p>2 rely on to produce that?</p> <p>3 A. We have medical records</p> <p>4 within the practice on all of our</p> <p>5 patients.</p> <p>6 Q. So someone would have to go</p> <p>7 through each record to determine when the</p> <p>8 patient last saw you, when she was</p> <p>9 contacted, what problems she was having,</p> <p>10 correct?</p> <p>11 A. That is correct.</p> <p>12 Q. Okay. And are you aware of</p> <p>13 literature that shows that most patients</p> <p>14 with mesh complications do not return to</p> <p>15 the original doctor who implanted the</p> <p>16 mesh product?</p> <p>17 MR. SNELL: Objection.</p> <p>18 Form. Foundation.</p> <p>19 THE WITNESS: I'm aware of</p> <p>20 literature that would speak to the</p> <p>21 opposite.</p> <p>22 BY MS. THOMPSON:</p> <p>23 Q. And what is that literature?</p> <p>24 If you could tell me, please.</p>	<p>1 Q. You can answer it again.</p> <p>2 MR. SNELL: Objection.</p> <p>3 Asked and answered.</p> <p>4 THE WITNESS: Can I ask that</p> <p>5 they simply read my answer back?</p> <p>6 MR. SNELL: Yes, you may.</p> <p>7 - - -</p> <p>8 (Whereupon, the court</p> <p>9 reporter read the following part</p> <p>10 of the record:</p> <p>11 "Question: And what records</p> <p>12 would you rely on to produce that?</p> <p>13 "Answer: We have medical</p> <p>14 records within the practice on all</p> <p>15 of our patients.</p> <p>16 "Question: So someone would</p> <p>17 have to go through each record to</p> <p>18 determine when the patient last</p> <p>19 saw you, when she was contacted,</p> <p>20 what problems she was having,</p> <p>21 correct?</p> <p>22 "Answer: That is correct.")</p> <p>23 - - -</p> <p>24 BY MS. THOMPSON:</p>
Page 163	Page 165
<p>1 A. Well, the first study, off</p> <p>2 the top of my head, I believe was the</p> <p>3 Abbott study, in which they commented, in</p> <p>4 the conclusions, that most people did</p> <p>5 return to their -- to their original</p> <p>6 provider initially.</p> <p>7 And I would say that,</p> <p>8 regardless, that would be highly atypical</p> <p>9 for my practice.</p> <p>10 Q. How do you know that?</p> <p>11 A. Because we have a rate of</p> <p>12 follow-up that is over 90 percent.</p> <p>13 Q. That if you went back and</p> <p>14 looked at every chart of every patient</p> <p>15 you've seen, you could determine whether</p> <p>16 that's true or not?</p> <p>17 MR. SNELL: Objection.</p> <p>18 Misstates.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. You can answer it.</p> <p>21 A. I thought that I already</p> <p>22 answered the question, I'm sorry.</p> <p>23 MR. SNELL: You did.</p> <p>24 BY MS. THOMPSON:</p>	<p>1 Q. Do you continue to follow up</p> <p>2 on patients who have left your practice,</p> <p>3 one, two, three, four, five, six, seven,</p> <p>4 eight, nine, ten years after the</p> <p>5 procedure?</p> <p>6 A. If they've left our</p> <p>7 practice, we would have no access to</p> <p>8 that.</p> <p>9 But, as I've stated</p> <p>10 earlier --</p> <p>11 Q. You don't need to state</p> <p>12 things that you've said earlier.</p> <p>13 So if a patient has left</p> <p>14 your practice because, say, they were</p> <p>15 cured of their stress incontinence at</p> <p>16 their follow-up visit, that's not a</p> <p>17 patient that you would continue to</p> <p>18 contact on a regular basis, is it?</p> <p>19 MR. SNELL: Form.</p> <p>20 THE WITNESS: So at the</p> <p>21 point of time, let's say that a</p> <p>22 patient was cured, I always offer</p> <p>23 to the patient that since we've</p> <p>24 done a surgical procedure that</p>

42 (Pages 162 to 165)

Marc Toggia, M.D.

Page 166	Page 168
<p>1 involves a permanent implant, that 2 it is my advice that they continue 3 to follow-up with us annually or 4 whether they -- any time that they 5 have a concern. 6 I also let them know that 7 I'm not going to harass them into 8 follow-up if they feel that they 9 are doing well. 10 Initially, we saw all of our 11 patients annually. And after 12 about five, six, seven years, 13 patients would literally say, 14 Doctor, can I say something to 15 you? I don't know why I have to 16 continue to come, I'm fine, it 17 costs me a co-pay to get here, I 18 have to take time off work. 19 BY MS. THOMPSON: 20 Q. So the answer to my 21 question, again -- 22 A. Yes. 23 Q. -- is that you don't contact 24 patients after they've left your</p>	<p>1 the Abbott study that you referred to 2 that said strictly the opposite of what I 3 said, that most patients don't return to 4 their original implanting surgeon and 5 show me in that article what you're 6 referring to? 7 A. I don't think I used the 8 word "strictly." 9 MS. THOMPSON: We can go off 10 the record, please. 11 VIDEO TECHNICIAN: We are 12 off the record. The time is 4:51 13 p.m. 14 - - - 15 (Whereupon, a discussion off 16 the record occurred.) 17 - - - 18 VIDEO TECHNICIAN: We are 19 back on the video record. The 20 time is 4:54 p.m. 21 THE WITNESS: So I just want 22 to clarify if I understand you 23 correctly. 24 So what you asked me was</p>
Page 167	Page 169
<p>1 practice, correct? 2 MR. SNELL: Objection to 3 form. Asked and answered. 4 MS. THOMPSON: He didn't 5 answer my question, Burt. 6 MR. SNELL: You're asking 7 the same question ten times. He's 8 already told you all the different 9 things that can happen. 10 BY MS. THOMPSON: 11 Q. Do you contact your patients 12 after they've left your practice or not? 13 MR. SNELL: Same objections. 14 THE WITNESS: I'll say the 15 same thing I said previously. 16 If a patient leaves our 17 practice, and by "leaves our 18 practice," means she informs us 19 that she is no longer requiring 20 our services, it would not be 21 appropriate for us to contact that 22 patient. 23 BY MS. THOMPSON: 24 Q. All right. Could you pull</p>	<p>1 whether or not -- you asked me 2 whether there was evidence that 3 patients that had a mesh 4 complication were unlikely to 5 return to their original provider? 6 BY MS. THOMPSON: 7 Q. I think what I said was the 8 majority of patients with mesh 9 complications do not return to their 10 original implanting doctor. 11 A. Okay. So I will correct 12 myself. 13 The Abbott study is not the 14 correct study to look at. I mis -- 15 misremembered, if that's a word, that the 16 Abbott study, the majority -- or half the 17 patients have come from an outside 18 system. 19 I will -- I will now refer 20 to the registry trials, if you'll -- and 21 there are several -- 22 Q. I'm not talking about a 23 patient that's in a trial. 24 A. No. Excuse me. Excuse me.</p>

43 (Pages 166 to 169)

Marc Toggia, M.D.

Page 170	Page 172
<p>1 I will -- when I say trial --</p> <p>2 MR. SNELL: Don't interrupt</p> <p>3 him when he's answering.</p> <p>4 THE WITNESS: -- I mean</p> <p>5 study.</p> <p>6 So there are -- there are --</p> <p>7 within the close -- excuse me.</p> <p>8 Within closed healthcare</p> <p>9 systems, an example would be</p> <p>10 Kaiser, and the other would be the</p> <p>11 healthcare systems of, say,</p> <p>12 Finland and Austria, within those</p> <p>13 closed systems, they would be able</p> <p>14 to capture -- and Canada would</p> <p>15 be -- would be another example,</p> <p>16 they would be able to capture that</p> <p>17 patient in the system no matter</p> <p>18 where they ended up within the</p> <p>19 system.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. Are you in Kaiser?</p> <p>22 A. I am not a Kaiser physician.</p> <p>23 Q. Are you in Finland?</p> <p>24 A. No, I'm not in Finland.</p>	<p>1 complication, that -- and you sought</p> <p>2 medical treatment, those are captured to</p> <p>3 a high degree of specificity.</p> <p>4 Q. And that's not responsive to</p> <p>5 any question I asked. So we'll move on.</p> <p>6 MR. SNELL: Move to strike.</p> <p>7 I think it was totally responsive</p> <p>8 to the question.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. Do you tell your patients</p> <p>11 that if they have complications that</p> <p>12 require a removal of the sling, that</p> <p>13 there may be multiple surgeries to</p> <p>14 correct that?</p> <p>15 MR. SNELL: I'm sorry, can</p> <p>16 you repeat that back?</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. Do you tell your patients</p> <p>19 that removal -- if they have</p> <p>20 complications that require removal of the</p> <p>21 device, it may take multiple surgeries to</p> <p>22 correct it?</p> <p>23 A. That is -- that is such a</p> <p>24 highly -- in my practice and experience,</p>
Page 171	Page 173
<p>1 Q. Are you in Austria?</p> <p>2 A. No.</p> <p>3 Q. Are you in Canada?</p> <p>4 A. No.</p> <p>5 Q. Thank you.</p> <p>6 A. But that's not the question</p> <p>7 that you asked me.</p> <p>8 Q. You've answered my question.</p> <p>9 A. I'm trying to answer the</p> <p>10 question, and you're trying to prevent me</p> <p>11 from answering.</p> <p>12 Q. What question is on the</p> <p>13 table?</p> <p>14 A. You asked me whether or not</p> <p>15 it is true that most patients who</p> <p>16 experience a complication are not then</p> <p>17 seen within the same system. And I'm</p> <p>18 telling you that in those circumstances,</p> <p>19 of which there is abundant data, some</p> <p>20 data that goes out to ten years, that</p> <p>21 that is not a correct statement. Those</p> <p>22 patients are captured.</p> <p>23 So, for example, if you're</p> <p>24 in Finland or Austria and you had a sling</p>	<p>1 that is such a highly unlikely</p> <p>2 occurrence, that that would not -- I</p> <p>3 would not speak to something that has</p> <p>4 that low of an occurrence.</p> <p>5 I would have difficulty</p> <p>6 thinking of a patient that underwent a</p> <p>7 TVT sling for the intended purpose of</p> <p>8 stress incontinence that would have</p> <p>9 required multiple procedures for that one</p> <p>10 sole thing.</p> <p>11 And in that regard, I would</p> <p>12 speak to the Abbott study, in which they</p> <p>13 acknowledge that for just sling-related</p> <p>14 procedures, typical management of medical</p> <p>15 complications were medical and not</p> <p>16 surgical and that, in general, were more</p> <p>17 easily -- easier resolved.</p> <p>18 Q. Easier -- more easily</p> <p>19 resolved than POP mesh?</p> <p>20 A. Correct. But --</p> <p>21 Q. Can you show me where in</p> <p>22 Abbott it tells it -- tells you that most</p> <p>23 of them are medically managed?</p> <p>24 A. Okay. Back to the Abbott</p>

44 (Pages 170 to 173)

Marc Toggia, M.D.

Page 174	Page 176
<p>1 study, on Page 163, last couple column. 2 Additionally, those women with 3 complications after sling-only procedures 4 were treated more often with medical 5 management and rarely required surgical 6 re-intervention. 7 Going -- 8 Q. That's comparing -- 9 A. Going -- 10 Q. That's comparing to the 11 prolapse mesh patients? 12 A. That was the objective of 13 the Abbott trial. 14 Second point, at the top of 15 that page. The treatment of stress 16 incontinence has a more predictable and 17 less severe course of complications 18 compared with that of synthetic mesh that 19 is used in the management of pelvic organ 20 prolapse. 21 Q. Correct, comparatively 22 speaking. 23 And the conclusion of the 24 study, just to clarify is, Most of the</p>	<p>1 objectives, study design, results and 2 conclusion on the first page. 3 A. The pattern of complaints 4 differed by the index of procedure. 5 I mean, I think, you know, 6 you're taking -- 7 Q. Most of the women -- 8 A. You're taking it out of -- 9 Q. Did I read it correctly? 10 Did I read the conclusions correctly? 11 That's the only question on the table. 12 A. The conclusions -- 13 MR. SNELL: I'm going to 14 object to the form. 15 THE WITNESS: The 16 conclusions are what are listed 17 under the comment, that's the 18 conclusion. 19 BY MS. THOMPSON: 20 Q. I didn't ask you -- I asked 21 you, did I read -- 22 A. You're reading the abstract. 23 You're reading an abstracted sentence. 24 Q. So you cannot answer the</p>
Page 175	Page 177
<p>1 women who seek management of synthetic 2 mesh complication after POP or SUI 3 surgery have severe complications that 4 require surgical intervention. A 5 significant proportion require greater 6 than one surgical procedure. 7 Did I read the conclusions 8 to that study correctly? 9 A. My apologies, I wasn't 10 following you. Where -- can you tell me 11 what page you're speaking to? 12 Q. The first page, the 13 conclusions of the study. Did I read it 14 correctly? That's the only question I 15 have for you. 16 A. The comment? 17 Q. The first page of the study, 18 under conclusions, did I read that 19 correctly? 20 A. Counselor, I'm trying not to 21 be difficult, but there's not a -- 22 there's not a subtitle that starts with 23 conclusions. 24 Q. In the abstract, it has,</p>	<p>1 question -- 2 A. I did answer the question. 3 Q. -- whether I read it 4 correctly or not? 5 A. I'm reading it under the 6 conclusion of the paper, okay? It's 7 right here. Additionally, those women 8 with complications after sling-only. We 9 are talking -- 10 Q. Okay. Let's move -- 11 A. -- about standalone sling 12 procedures -- 13 Q. Let's move on. 14 A. -- correct? 15 Q. Let's move on. 16 Do you tell your patients 17 that the polypropylene mesh and TVT 18 device creates chronic inflammation? 19 MR. SNELL: Objection. 20 Asked and answered. 21 MS. THOMPSON: No, I asked 22 about chronic foreign body 23 reaction. Those are two different 24 things.</p>

45 (Pages 174 to 177)

Marc Toggia, M.D.

Page 178	Page 180
<p>1 MR. SNELL: I stand</p> <p>2 corrected. I thought you said</p> <p>3 that.</p> <p>4 THE WITNESS: Based upon our</p> <p>5 experience in the last 17 years,</p> <p>6 with nearly 2,500 procedures, we</p> <p>7 have not observed any chronic</p> <p>8 inflammation as it relates to the</p> <p>9 retropubic TVT, and, therefore, we</p> <p>10 don't speak to them about</p> <p>11 something that we have not seen.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. If Ethicon had information</p> <p>14 about chronic inflammation, is that</p> <p>15 something that you, as a doctor, would</p> <p>16 want to know?</p> <p>17 A. As an expert in this field,</p> <p>18 I would not rely upon Ethicon for that</p> <p>19 information. I seek that information</p> <p>20 myself, formulating that opinion from</p> <p>21 high-quality studies.</p> <p>22 Q. Is that information patients</p> <p>23 would want to know?</p> <p>24 A. I think patients would --</p>	<p>1 percent.</p> <p>2 Q. What else?</p> <p>3 A. I believe that we did</p> <p>4 discuss this earlier on, but it was</p> <p>5 specific to myself.</p> <p>6 There's always a risk of</p> <p>7 bleeding, that is something that is</p> <p>8 discussed with all patients. We tell</p> <p>9 them about our experience with bleeding,</p> <p>10 that we see it a little more commonly in</p> <p>11 the younger patients.</p> <p>12 We talk about the potential</p> <p>13 risk that, maybe, the symptom improvement</p> <p>14 may not be as much as they want and that</p> <p>15 there are occasions where a second</p> <p>16 procedure might need to be performed.</p> <p>17 Conversely, we tell people</p> <p>18 that there is a small risk for voiding</p> <p>19 dysfunction and that, at times, that will</p> <p>20 require re-intervention for that reason.</p> <p>21 There is a risk for vaginal</p> <p>22 perforation, urethral perforation, nerve</p> <p>23 injury, bowel injury. And those are all</p> <p>24 discussed with the patients.</p>
Page 179	Page 181
<p>1 would love to know that I spend the time</p> <p>2 seeking out high-quality data and look at</p> <p>3 long-term studies and rely upon those</p> <p>4 type of systematic review groups when I</p> <p>5 present the safety profile of that</p> <p>6 procedure.</p> <p>7 Q. Do any of your patients have</p> <p>8 complications after a TVT procedure?</p> <p>9 A. Patients can have</p> <p>10 complications after any surgical</p> <p>11 procedure.</p> <p>12 Q. That wasn't my question.</p> <p>13 Have any of your patients</p> <p>14 had complications after a TVT procedure</p> <p>15 that you've performed?</p> <p>16 A. Yes. As I've stated in</p> <p>17 my --</p> <p>18 Q. Okay. That's -- that's all</p> <p>19 I need.</p> <p>20 And what are those</p> <p>21 complications?</p> <p>22 A. The most common complication</p> <p>23 that we see would be injury of the</p> <p>24 bladder, which, in our hands, is about 1</p>	<p>1 We speak about other risks</p> <p>2 such as pain with sexual intercourse,</p> <p>3 more specifically, relative to the other</p> <p>4 procedures, and that in our experience,</p> <p>5 and according to high-quality data, the</p> <p>6 rate of dyspareunia is exceedingly low</p> <p>7 with the retropubic TVT sling.</p> <p>8 Q. Is it your opinion that when</p> <p>9 complications occur it's because the</p> <p>10 surgeon placed the device improperly?</p> <p>11 A. I would say, in most cases,</p> <p>12 it is a direct result of -- it's user</p> <p>13 dependent, and I make that point in my</p> <p>14 paper, in my --</p> <p>15 Q. And that would include the</p> <p>16 complications that you've had with your</p> <p>17 procedures?</p> <p>18 A. Correct.</p> <p>19 Q. And how many TVT devices</p> <p>20 have you removed or performed some kind</p> <p>21 of revision surgery on?</p> <p>22 A. I think it's best to answer</p> <p>23 that sort of on an annual basis. Again,</p> <p>24 understanding that I've been performing</p>

46 (Pages 178 to 181)

Marc Toggia, M.D.

Page 182	Page 184
<p>1 this procedure over a 17-year period of 2 time. 3 I would say, in the average 4 year, that probably ranges from zero to 5 one. 6 Q. So only zero to one time per 7 year are you doing any corrective surgery 8 on a TVT device? 9 MR. SNELL: Objection. 10 Misstates. 11 BY MS. THOMPSON: 12 Q. Zero to one per year -- 13 MR. SNELL: You're changing 14 your question. You're asking 15 about TVT Retropubic and then the 16 next question is a TVT device, 17 which can be -- 18 MS. THOMPSON: Sorry. I'll 19 rephrase it. 20 And, again, if you'll just 21 ask me if you don't understand a 22 question. 23 THE WITNESS: I understand. 24 MS. THOMPSON: Then you can</p>	<p>1 that you are considered one of the 2 leading experts in the Greater 3 Philadelphia region on surgical revision 4 of complications related to vaginal mesh 5 procedures. 6 Is that a true -- true 7 statement? 8 A. That is a true statement. 9 Q. And why is there a need for 10 experts on surgical revision of 11 complications related to vaginal mesh 12 procedures? 13 A. I think there are experts 14 required for the management of any kind 15 of surgical revision of problems that can 16 occur. 17 Q. Now, I've never seen someone 18 say that they are an expert in the 19 surgical management of complications 20 related to a Burch or to autologous 21 fascial sling or to native tissue 22 repairs. 23 Explain to me why an expert 24 is needed for the management of vaginal</p>
Page 183	Page 185
<p>1 object to form. He can ask me if 2 he doesn't understand it. 3 THE WITNESS: I'm listening 4 to what you're asking. 5 MS. THOMPSON: Because I 6 think you knew -- I think you knew 7 what I meant when I said that. 8 BY MS. THOMPSON: 9 Q. So zero to one TVT 10 Retropubic devices are how many you are 11 removing in a typical year; is that 12 correct? 13 A. Well, I don't think that 14 you're accurate, the word "removal." 15 It's removal or revision. 16 I would say that probably 17 once a year, or so, are we having to 18 surgically revise a TVT device -- excuse 19 me, a TVT procedure. 20 And I'm -- again, for the I 21 remember sake of argument, I'm speaking 22 about the retropubic TVT procedure that 23 we are doing for stress incontinence. 24 Q. In your report, you said</p>	<p>1 mesh complications. 2 MR. SNELL: Objection. 3 Form. 4 THE WITNESS: In that 5 context, I would hold myself out 6 in those fields. The -- the need 7 to re-intervene is identical, 8 practically speaking, amongst the 9 three most common 10 anti-incontinence procedure, 11 whether that be a Burch -- I 12 probably revise more Burches, 13 fascial slings, bladder neck 14 slings than I do midurethral 15 slings. 16 BY MS. THOMPSON: 17 Q. So what you intended to say 18 is that you're one of the leading experts 19 on surgical revisions of complications 20 for any pelvic procedures, not vaginal 21 mesh procedures? 22 A. I don't -- pelvic procedures 23 is a little bit too broad. 24 With regard to prior</p>

47 (Pages 182 to 185)

Marc Toggia, M.D.

Page 186	Page 188
<p>1 surgical intervention for pelvic floor --</p> <p>2 surgery for pelvic floor dysfunction, I</p> <p>3 probably have as much experience as</p> <p>4 anyone else in the area. And that is a</p> <p>5 frequent source for referral.</p> <p>6 Q. You, I believe, said in your</p> <p>7 report that you had done 3,000 patients</p> <p>8 with TVT, but that may have been all</p> <p>9 urethral slings, it doesn't make too</p> <p>10 much --</p> <p>11 A. I think --</p> <p>12 Q. -- difference for my</p> <p>13 question.</p> <p>14 A. Well, I think 3,000 may</p> <p>15 refer to everything, including</p> <p>16 sacrocolpopexy performed with mesh. I</p> <p>17 think it's 3,000 mesh related procedures.</p> <p>18 That would include the entire scope.</p> <p>19 Q. Okay.</p> <p>20 A. If you just want to accept</p> <p>21 me at my word, I think that's -- I'm</p> <p>22 pretty --</p> <p>23 Q. We'll go ahead and find it.</p> <p>24 A. That one I'm pretty sure of,</p>	<p>1 A. That is correct.</p> <p>2 Q. -- and have yet to observe a</p> <p>3 single case -- now I want to go through</p> <p>4 some of these.</p> <p>5 How do you define -- define</p> <p>6 "mesh rejection"?</p> <p>7 A. Since I haven't seen a case</p> <p>8 of that, a case in which there was overt</p> <p>9 expulsion of the mesh, in which there was</p> <p>10 complete failure of primary healing, in</p> <p>11 which there was systemic response of an</p> <p>12 inflammatory reaction.</p> <p>13 Q. So your definition of</p> <p>14 rejection, then, is overt expulsion and</p> <p>15 not -- that would not include erosion</p> <p>16 into any organ, correct?</p> <p>17 A. My definition is just,</p> <p>18 succinctly, would be evidence of overt</p> <p>19 graft versus host disease.</p> <p>20 Q. And what symptoms would the</p> <p>21 patient present with --</p> <p>22 A. Excuse me, host versus</p> <p>23 graft.</p> <p>24 Q. I knew what you meant.</p>
Page 187	Page 189
<p>1 because I said it.</p> <p>2 Q. Well, whatever it is, it's</p> <p>3 in your report. We can look it up later.</p> <p>4 You said in those 3,000</p> <p>5 patients --</p> <p>6 MR. SNELL: Where are you</p> <p>7 at, counsel? Just so --</p> <p>8 MS. THOMPSON: Okay. I'll</p> <p>9 have to find it. I thought I had</p> <p>10 it underlined.</p> <p>11 THE WITNESS: I don't think</p> <p>12 I said anything beyond the fact</p> <p>13 that I had experience in 3,000</p> <p>14 patients. I don't think I went --</p> <p>15 I did not go on.</p> <p>16 BY MS. THOMPSON:</p> <p>17 Q. On Page 9, the last</p> <p>18 sentence. I have personally used it --</p> <p>19 and I think that's referring to</p> <p>20 polypropylene mesh, I guess?</p> <p>21 A. That would be correct.</p> <p>22 Q. -- as my primary implant</p> <p>23 material in my patients for over 15 years</p> <p>24 in more than 3,000 patients --</p>	<p>1 What symptoms would the</p> <p>2 patient present with, in your opinion?</p> <p>3 A. There could be expulsion of</p> <p>4 the material, there could be complete</p> <p>5 failure of primary healing, recurrent --</p> <p>6 or some kind of systemic response,</p> <p>7 anaphylaxis.</p> <p>8 Q. And by "overt expulsion" you</p> <p>9 are not referring to erosion into the</p> <p>10 vagina, the urethra or bladder?</p> <p>11 A. Thank you for clarifying</p> <p>12 that.</p> <p>13 So rejection is rejection,</p> <p>14 exposure is a different phenomenon,</p> <p>15 correct.</p> <p>16 Q. And what testing did you do</p> <p>17 on those 3,000 patients to determine</p> <p>18 there wasn't a host versus graft</p> <p>19 condition?</p> <p>20 A. I don't think it would be</p> <p>21 ethical, counselor, for me to test --</p> <p>22 test -- somehow subject a test on an</p> <p>23 asymptomatic patient. And I think that a</p> <p>24 large body of the literature cited by</p>

48 (Pages 186 to 189)

Marc Toggia, M.D.

Page 190	Page 192
<p>1 your experts speak to the fact that they</p> <p>2 were unable to do that kind of testing</p> <p>3 because of ethical considerations.</p> <p>4 Q. You would agree with me,</p> <p>5 though, that rejection is an immunologic</p> <p>6 response to a foreign body?</p> <p>7 A. I think --</p> <p>8 MR. SNELL: Objection to</p> <p>9 form.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: I think that's</p> <p>12 one -- one type of rejection might</p> <p>13 be immunologic, yes.</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. And are you aware of</p> <p>16 literature that tested, immunologically</p> <p>17 and/or histologically, for a rejection</p> <p>18 condition?</p> <p>19 MR. SNELL: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: There is no</p> <p>22 high-quality literature or data</p> <p>23 that suggests that that phenomena</p> <p>24 occurs with the TVT device when</p>	<p>1 you --</p> <p>2 Q. Mr. Snell can ask you that</p> <p>3 question, if you he wants to, at the end.</p> <p>4 A. So when you have Level 1 --</p> <p>5 Q. I have not asked you that</p> <p>6 question.</p> <p>7 A. Please allow me to finish my</p> <p>8 answer, counselor.</p> <p>9 When you have -- because</p> <p>10 this is -- this is paramount to my</p> <p>11 methodology.</p> <p>12 When you have Level 1 data,</p> <p>13 Level 5 data doesn't count, okay?</p> <p>14 Additionally, you can never</p> <p>15 derive clinical implications or draw</p> <p>16 clinical conclusions from Level 5 data.</p> <p>17 That is implicit in the weak design of</p> <p>18 that study. Every author of those papers</p> <p>19 makes that disclosure, as far as the --</p> <p>20 as far as the ramifications.</p> <p>21 In fact, I will point to</p> <p>22 Clave, which I cited in my --</p> <p>23 MS. THOMPSON: This is</p> <p>24 really all nonresponsive. So</p>
Page 191	Page 193
<p>1 used for the indication of stress</p> <p>2 incontinence.</p> <p>3 The long-term registry</p> <p>4 trials, which have followed out to</p> <p>5 ten years, as well as the</p> <p>6 additional data out to 17 years,</p> <p>7 do not raise any concern,</p> <p>8 clinically, that those -- that</p> <p>9 that phenomena exists.</p> <p>10 Now, I have reviewed the</p> <p>11 information provided by your</p> <p>12 experts, in which they were to</p> <p>13 hypothesize that. That</p> <p>14 information is Level 5 evidence.</p> <p>15 Now, let me just show you</p> <p>16 that.</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. I don't need you to show me.</p> <p>19 A. No, no --</p> <p>20 Q. I didn't ask --</p> <p>21 A. -- I do.</p> <p>22 Q. -- any question about the</p> <p>23 level of evidence.</p> <p>24 A. But I have to explain to</p>	<p>1 if --</p> <p>2 MR. SNELL: No, you asked</p> <p>3 him do you know of literature.</p> <p>4 And he's telling you about</p> <p>5 literature.</p> <p>6 THE WITNESS: Yes.</p> <p>7 MR. SNELL: And he's</p> <p>8 saying --</p> <p>9 MS. THOMPSON: I'm asked him</p> <p>10 about literature about immune</p> <p>11 response to foreign body.</p> <p>12 MR. SNELL: He's telling</p> <p>13 you. He saw what your experts</p> <p>14 have pointed to --</p> <p>15 MS. COPE: Should I start</p> <p>16 talking, too? You seem to speak</p> <p>17 freely for him.</p> <p>18 MR. SNELL: I'm not speaking</p> <p>19 for him. You asked me a question,</p> <p>20 Margaret, I'm going to give you an</p> <p>21 answer. Don't ask me a question,</p> <p>22 then.</p> <p>23 MS. THOMPSON: Okay. I'm</p> <p>24 going to request more time if he</p>

49 (Pages 190 to 193)

Marc Toggia, M.D.

Page 194	Page 196
<p>1 is going to continue to not answer 2 my question. 3 THE WITNESS: Counselor, I 4 am -- 5 MS. THOMPSON: We'll go off 6 the record, and he can look up his 7 literature that he wants to talk 8 about. 9 VIDEO TECHNICIAN: We are 10 off the record. The time is 5:15 11 p.m. 12 - - - 13 (Whereupon, a discussion off 14 the record occurred.) 15 - - - 16 VIDEO TECHNICIAN: We are 17 back on the video record. 18 THE WITNESS: The literature 19 that we are discussing here is not 20 applicable to TVT, okay? 21 BY MS. THOMPSON: 22 Q. Okay. All right. 23 A. And it does not have 24 sufficient weight or evidence that you</p>	<p>1 poor-quality study. 2 Q. And is there evidence to the 3 contrary, that there is no immune -- 4 significant immune response to the 5 polypropylene mesh in the TVT that you 6 are aware of? 7 A. Can I speak to -- 8 MR. SNELL: Object to form. 9 THE WITNESS: Can I speak to 10 the Wang study, please? 11 BY MS. THOMPSON: 12 Q. No, I -- just answer my 13 question, please. 14 And the question is, is 15 there-- 16 A. Hold on. I'm sorry, I'm 17 going to ask you to pause. 18 You did ask me about the 19 Wang study, I want to make sure -- 20 Q. I asked you if you were 21 aware of it. I have not asked you any 22 questions about the Wang study, other 23 than, are you aware of it? 24 MR. SNELL: Actually, no.</p>
Page 195	Page 197
<p>1 can draw those conclusions. 2 Q. Is your opinion that Level 5 3 evidence regarding safety issues is also 4 worthless? 5 MR. SNELL: Form. 6 Objection. 7 THE WITNESS: When you have 8 Level 1 evidence on safety, then 9 the Level 5 evidence is not 10 considered to be important. 11 BY MS. THOMPSON: 12 Q. Do you believe that we have 13 Level 1 evidence on the safety of the 14 TVT -- 15 A. Absolutely. 16 Q. -- yes or no? 17 A. Absolutely. 18 Q. Okay. There's an article, 19 Wang, I believe it's on your reliance 20 list. 21 A. Yes. 22 Q. Do you believe that's not a 23 quality study? 24 A. That is an extremely</p>	<p>1 You -- 2 THE WITNESS: You asked me 3 about the quality of the evidence. 4 I'm going to tell you the answer, 5 and I'm going to tell you what I'm 6 basing my answer on. 7 BY MS. THOMPSON: 8 Q. I asked you -- I'm asking 9 you about the evidence that shows that 10 there is no immune response to the 11 foreign body. That's what I would like 12 for you to answer, the question, and tell 13 me if you have evidence that there is no 14 immune response to the foreign material 15 in the TVT. 16 A. The long-term safety 17 studies -- excuse me. The long-term 18 Level 1 evidence studies speak to the 19 lack of a significant immune response. 20 In addition -- 21 Q. Okay. Can you -- 22 A. In addition -- 23 MR. SNELL: Don't stop him. 24 THE WITNESS: -- the</p>

50 (Pages 194 to 197)

Marc Toggia, M.D.

Page 198	Page 200
<p>1 systematic reviews speak to the 2 fact, and this includes -- and 3 this is consistent with what is 4 stated by the FDA, what is stated 5 by NICE, what is stated by AUA, 6 AUGS, and SUFU, that there is -- 7 that polypropylene mesh, 8 macroporous, as used with the TVT 9 device for its intended purpose, 10 is the most biomechanic -- 11 biocompatible material. 12 By definition, biocompatible 13 speaks to host tolerance and the 14 lack of immunologic response. 15 BY MS. THOMPSON: 16 Q. Can you show me, in any of 17 those things that you just rattled off, 18 where it states that there is no 19 immunologic response to polypropylene 20 mesh in the TVT device? 21 MR. SNELL: Objection to 22 form. 23 BY MS. THOMPSON: 24 Q. I'm looking for immunologic</p>	<p>1 material as relates to the TVT 2 device, which has been in 3 development over 20 years, is 4 broad and extensive and worldwide. 5 And, you know, unfortunately, 6 there is a lot of material. 7 And while I'm well versed in 8 it, it still takes me a while to 9 figure out exactly the location of 10 the statements that I have in 11 mind. 12 Why don't you go back off 13 the record? 14 MS. THOMPSON: I should be 15 the one who directs the 16 videographer, if you don't mind. 17 THE WITNESS: I'm sorry. 18 I'm just trying -- I'm just trying 19 to be respectful of people's time, 20 and I'm apologizing for the amount 21 of time it's taking. I'm just -- 22 I want you to know I'm not doing 23 this to be obstructive. 24 BY MS. THOMPSON:</p>
Page 199	Page 201
<p>1 response, which is what rejection or 2 graft versus -- versus host versus graft 3 response is. 4 MR. SNELL: Objection to 5 form. 6 THE WITNESS: Can we go off 7 record? 8 MS. THOMPSON: Off the 9 record, please. 10 VIDEO TECHNICIAN: We are 11 off the record. The time is 5:19 12 p.m. 13 - - - 14 (Whereupon, a discussion off 15 the record occurred.) 16 - - - 17 VIDEO TECHNICIAN: We are 18 back on the video record. 19 THE WITNESS: Yes. Again, I 20 am -- I am trying to be extremely 21 respectful of everybody's time, 22 and acknowledge that this is 23 Friday. 24 Unfortunately, the volume of</p>	<p>1 Q. And, I mean, we can just 2 concede that you have not been able to 3 find anything on that particular issue in 4 the time allotted. 5 A. If I can -- if I cannot 6 produce this within the next several 7 minutes, I'm happy to move on, again, out 8 of respect for everybody's time. 9 Why don't you go ahead and 10 ask me the question, counselor? 11 Q. The next question? 12 A. No. 13 Q. The previous question that 14 we've been -- are we on the record? 15 MS. THOMPSON: Are we on the 16 record, Greg? 17 VIDEO TECHNICIAN: We're on 18 the record. 19 THE WITNESS: I'm sorry. 20 BY MS. THOMPSON: 21 Q. Are you ready to move to the 22 next question? 23 A. Yes. 24 Q. Hopefully, we won't spend as</p>

51 (Pages 198 to 201)

Marc Toggia, M.D.

Page 202	Page 204
<p>1 much time on the other things that you've</p> <p>2 said you've not seen one single patient</p> <p>3 out of your 3,000 that have had these</p> <p>4 particular conditions, you said that you</p> <p>5 have yet to observe a single case of</p> <p>6 chronic foreign body reaction.</p> <p>7 How did you determine that</p> <p>8 you have not had a single patient, out of</p> <p>9 3,000, that has had a chronic foreign</p> <p>10 body reaction to mesh?</p> <p>11 A. So clinical suspicions that</p> <p>12 one might be experiencing a reaction that</p> <p>13 would be classified as a chronic foreign</p> <p>14 body reaction would be things like</p> <p>15 chronic nonhealing of a wound, persistent</p> <p>16 erythema, fluctuance, pain, chronic</p> <p>17 drainage.</p> <p>18 Q. But you would agree with me</p> <p>19 that chronic foreign body reaction is a</p> <p>20 histologic diagnosis, would you not?</p> <p>21 MR. SNELL: Form.</p> <p>22 Objection.</p> <p>23 THE WITNESS: I would say</p> <p>24 that it is -- it is something that</p>	<p>1 It is both.</p> <p>2 MR. SNELL: Would you read</p> <p>3 it --</p> <p>4 THE WITNESS: It is</p> <p>5 clinical --</p> <p>6 MR. SNELL: Would you read</p> <p>7 it back?</p> <p>8 MS. THOMPSON: No.</p> <p>9 MR. SNELL: Go ahead and --</p> <p>10 go ahead and answer it again.</p> <p>11 BY MS. THOMPSON:</p> <p>12 Q. Okay. All right. So of</p> <p>13 these 3,000 patients that you've never</p> <p>14 seen a chronic foreign body reaction, are</p> <p>15 you aware that there's literature that</p> <p>16 states that 100 percent of women with</p> <p>17 pelvic mesh in their bodies have a</p> <p>18 chronic foreign body reaction?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. 100 percent?</p> <p>22 Are you aware of that</p> <p>23 literature?</p> <p>24 MR. SNELL: Objection. Form</p>
Page 203	Page 205
<p>1 always has a clinical presentation</p> <p>2 and then would be confirmed on it.</p> <p>3 Now, in contrast, we have</p> <p>4 seen this with other implanted</p> <p>5 material. So I am very familiar</p> <p>6 with the presentation. In fact,</p> <p>7 I've published on the</p> <p>8 presentations within the pelvic</p> <p>9 floor, in the vaginal space, as it</p> <p>10 relates to what we referred to, at</p> <p>11 the time, was chronic</p> <p>12 granulomatous response to a</p> <p>13 foreign body within the context of</p> <p>14 reconstructive pelvic surgery.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. I don't think you answered</p> <p>17 my question.</p> <p>18 Foreign body reaction is a</p> <p>19 histologic pathologic diagnosis, correct?</p> <p>20 MR. SNELL: Asked and</p> <p>21 answered.</p> <p>22 MS. THOMPSON: If you got</p> <p>23 the answer, I sure didn't.</p> <p>24 THE WITNESS: It is both.</p>	<p>1 and foundation.</p> <p>2 THE WITNESS: Rephrase your</p> <p>3 question, please.</p> <p>4 BY MS. THOMPSON:</p> <p>5 Q. Are you aware -- are you</p> <p>6 aware of literature that states that 100</p> <p>7 percent of women with pelvic mesh have a</p> <p>8 chronic foreign body reaction to the</p> <p>9 mesh?</p> <p>10 MR. SNELL: Same objection</p> <p>11 to form and foundation.</p> <p>12 THE WITNESS: If you have a</p> <p>13 foreign body implanted in your</p> <p>14 body, chronically, there will</p> <p>15 always be histologic evidence of</p> <p>16 the body's reaction surrounding</p> <p>17 the mesh or the material.</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. So that's really --</p> <p>20 A. That -- that is not germane</p> <p>21 or related clinically, nor can you take</p> <p>22 inflammation that just randomly produces</p> <p>23 that kind of in vitro, again, Level 5</p> <p>24 evidence, you cannot make clinical</p>

52 (Pages 202 to 205)

Marc Toggia, M.D.

Page 206	Page 208
<p>1 inference. There's not enough power to</p> <p>2 that study.</p> <p>3 The only way that you could</p> <p>4 make that is by examining Level 1</p> <p>5 evidence and deriving that.</p> <p>6 Q. Is there Level 1 evidence</p> <p>7 that states that there is not a chronic</p> <p>8 foreign body reaction to mesh; yes or no?</p> <p>9 A. There is -- there is a</p> <p>10 chronic -- excuse me.</p> <p>11 There is -- the body does</p> <p>12 respond, in 100 percent of patients, but</p> <p>13 there's no negative clinical sequelae.</p> <p>14 Q. So your statement that you</p> <p>15 have not had a single case of chronic</p> <p>16 foreign body reaction, that's not really</p> <p>17 what you mean, right?</p> <p>18 A. No, clinically based. I'm</p> <p>19 speaking to clinical medicine, clinical</p> <p>20 problems.</p> <p>21 Q. And you know that for a</p> <p>22 fact, out of your 3,000 patients?</p> <p>23 A. To the best of my knowledge,</p> <p>24 a patient has never presented to me with</p>	<p>1 There is no non-important death.</p> <p>2 You don't -- you don't need Level</p> <p>3 1 evidence to tell you that a</p> <p>4 death has occurred.</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. And that's something that</p> <p>7 you would want to know, correct?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. As a doctor and a patient?</p> <p>11 MR. SNELL: Objection.</p> <p>12 Form.</p> <p>13 THE WITNESS: If a patient</p> <p>14 of mine were to die as a result of</p> <p>15 one of my procedures, I would</p> <p>16 absolutely want to know about the</p> <p>17 occurrence of the death and the</p> <p>18 cause of death.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. I'm talking about published</p> <p>21 in the literature.</p> <p>22 Would you want to know other</p> <p>23 doctors' patients who have died as a</p> <p>24 result of a TVT or another mesh</p>
Page 207	Page 209
<p>1 a chronic or acute medical syndrome in</p> <p>2 which we could identify, as the source, a</p> <p>3 chronic inflammatory reaction.</p> <p>4 Q. And I think that's a little</p> <p>5 different from what you stated here --</p> <p>6 A. No, counselor.</p> <p>7 Q. -- so I appreciate that.</p> <p>8 A. No. My -- my -- if I speak</p> <p>9 to my clinical experience, it's clinical.</p> <p>10 It's not stuff that I'm doing in a lab.</p> <p>11 I think that's quite clear.</p> <p>12 Q. Is less than Level 1</p> <p>13 evidence important if you're reporting a</p> <p>14 death from a minor procedure like the</p> <p>15 TVT?</p> <p>16 MR. SNELL: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: Well, I</p> <p>19 think -- I think you're using -- I</p> <p>20 think you're using the -- I think</p> <p>21 that you're using the clinical --</p> <p>22 clinical evidence pyramid out of</p> <p>23 context here.</p> <p>24 All deaths are important.</p>	<p>1 procedure?</p> <p>2 MR. SNELL: Object to form.</p> <p>3 THE WITNESS: You know, I</p> <p>4 think that I would be aware of</p> <p>5 that, yes.</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. That wasn't my question,</p> <p>8 would you be aware of it.</p> <p>9 Is it something that you</p> <p>10 would want to know and see published?</p> <p>11 MR. SNELL: Same objection.</p> <p>12 THE WITNESS: I don't</p> <p>13 necessarily think it needs to be</p> <p>14 published. If someone dies at the</p> <p>15 hospital next to me, I'm not going</p> <p>16 to wait until it's published</p> <p>17 before I think about what had</p> <p>18 occurred.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Well, what if a patient dies</p> <p>21 in Atlanta, Georgia, which happened a</p> <p>22 little while ago, is that something that</p> <p>23 you would want to know about?</p> <p>24 MR. SNELL: Objection.</p>

53 (Pages 206 to 209)

Marc Toggia, M.D.

Page 210	Page 212
<p>1 Form. Vague. Lacks foundation.</p> <p>2 THE WITNESS: I don't --</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. From a TVT.</p> <p>5 A. I don't know -- I mean, that</p> <p>6 an isolated case that happened</p> <p>7 elsewhere -- I mean, would I want to</p> <p>8 know? I mean, I wouldn't close my ears</p> <p>9 if someone told me about the problem.</p> <p>10 But had I not heard about</p> <p>11 it, I wouldn't say that a foul was</p> <p>12 committed.</p> <p>13 Q. Do you routinely send the</p> <p>14 specimens that you remove when you -- of</p> <p>15 mesh for histologic exam?</p> <p>16 A. We do routinely send -- send</p> <p>17 specimens to the lab for identification.</p> <p>18 Q. Have you ever looked at the</p> <p>19 slides?</p> <p>20 A. I have not looked at the</p> <p>21 slides.</p> <p>22 Q. You've never looked at an</p> <p>23 explanted mesh under the microscope?</p> <p>24 A. I have never looked at an</p>	<p>1 midurethral slings?</p> <p>2 MR. SNELL: Form.</p> <p>3 THE WITNESS: In what</p> <p>4 context? In the treatment of</p> <p>5 stress urinary incontinence in</p> <p>6 women?</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. In the treatment of stress</p> <p>9 urinary incontinence?</p> <p>10 A. TVT is only one of several</p> <p>11 procedures that is effective for the</p> <p>12 treatment of female stress incontinence.</p> <p>13 Q. Okay. The Burch procedure</p> <p>14 would be one of those, correct?</p> <p>15 A. That is correct.</p> <p>16 Q. And an autologous sling</p> <p>17 would be one of those, correct?</p> <p>18 A. That is correct.</p> <p>19 Q. And there are actually</p> <p>20 nonsurgical treatments for stress urinary</p> <p>21 incontinence as well, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And can we agree that they</p> <p>24 have equivalent efficacy?</p>
Page 211	Page 213
<p>1 explanted mesh under the microscope.</p> <p>2 Q. So you really don't know</p> <p>3 what they look like, do you, under the</p> <p>4 microscope?</p> <p>5 A. Yes, I do. They are in all</p> <p>6 these articles. There are clear</p> <p>7 photomicrographs on there with accurate</p> <p>8 pathologic descriptions. That's not what</p> <p>9 you asked me.</p> <p>10 Q. But you disagree with the</p> <p>11 pathological descriptions in the</p> <p>12 literature?</p> <p>13 A. You and I are talking about</p> <p>14 different things.</p> <p>15 I have already told you that</p> <p>16 a foreign material in the body, you will</p> <p>17 see evidence of that response. You have</p> <p>18 to see evidence. There -- it's a foreign</p> <p>19 body and there is -- and there is a</p> <p>20 thing.</p> <p>21 But it's not a clinically</p> <p>22 significant observation.</p> <p>23 Q. All right. You agree with</p> <p>24 me that there are alternatives to</p>	<p>1 A. Across the board, efficacy</p> <p>2 is similar. Again, you do a</p> <p>3 meta-analysis, you overweight</p> <p>4 higher-quality data, you'll get -- you'll</p> <p>5 get recommendations that say, I favor one</p> <p>6 or the other.</p> <p>7 But I think it's a</p> <p>8 reasonable statement, as presented in the</p> <p>9 short-term, that the effectiveness, in</p> <p>10 the short-term across the procedures</p> <p>11 are -- demonstrate similar efficacy.</p> <p>12 Q. Do you know Mickey Curran?</p> <p>13 A. Yes.</p> <p>14 Q. I believe you've published</p> <p>15 with him on one of your papers; is that</p> <p>16 correct?</p> <p>17 A. I've published with Mickey</p> <p>18 on several papers, correct.</p> <p>19 Q. I want to read you and</p> <p>20 statement and I want you to tell me</p> <p>21 whether you agree with it or not, okay?</p> <p>22 A. May I ask who is making the</p> <p>23 statement?</p> <p>24 Q. Well, Dr. Curran is making</p>

54 (Pages 210 to 213)

Marc Toggia, M.D.

Page 214	Page 216
<p>1 the statement.</p> <p>2 A. Thank you. I just want to</p> <p>3 make sure it wasn't me making the</p> <p>4 statement.</p> <p>5 Q. But it wouldn't matter, I</p> <p>6 guess, for the purpose of whether you</p> <p>7 agree with it or not.</p> <p>8 In our opinion, the</p> <p>9 autologous pubovaginal sling is</p> <p>10 appropriate for patients with stress</p> <p>11 urinary incontinence who declined to have</p> <p>12 synthetic material implanted because of</p> <p>13 concerns related to long-term placement</p> <p>14 of synthetic mesh.</p> <p>15 Would you agree with that</p> <p>16 statement?</p> <p>17 MR. SNELL: Objection to the</p> <p>18 form.</p> <p>19 Go ahead.</p> <p>20 THE WITNESS: Can you tell</p> <p>21 me the year that that was</p> <p>22 published?</p> <p>23 MS. THOMPSON: 2012, I</p> <p>24 believe.</p>	<p>1 paid for a Burch?</p> <p>2 A. I would suspect that the</p> <p>3 reimbursement for the Burch is likely to</p> <p>4 be a little bit higher.</p> <p>5 But I do want to -- I do</p> <p>6 want to clarify something. And I suspect</p> <p>7 that with your background, you would</p> <p>8 understand what I'm about to say.</p> <p>9 We're not paid for the</p> <p>10 procedure. The reimbursement for, say,</p> <p>11 the surgery encompasses all services that</p> <p>12 we provide, 24 hours prior to the</p> <p>13 procedure for the actual procedure,</p> <p>14 whatever amount of postoperative care is</p> <p>15 deemed necessary and pretty much all care</p> <p>16 out to about 90 days.</p> <p>17 So the percentage of what I</p> <p>18 just mentioned that's specific for</p> <p>19 placing the procedure, it's probably half</p> <p>20 that, if you're looking for that specific</p> <p>21 of information.</p> <p>22 Q. And how long did it take you</p> <p>23 to place a TVT?</p> <p>24 A. In my hands, a TVT can be</p>
Page 215	Page 217
<p>1 THE WITNESS: I think that's</p> <p>2 a relatively reasonable statement.</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Reasonable?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. Thank you. I'll just</p> <p>7 check on that date for you real quick.</p> <p>8 2012.</p> <p>9 A. Okay. Thank you.</p> <p>10 Q. How much are you paid for</p> <p>11 placing a TVT on average?</p> <p>12 A. The reimbursement for the</p> <p>13 TVT -- there is no -- there is no</p> <p>14 specific procedure of TVT. So it's a</p> <p>15 pubovaginal sling procedure.</p> <p>16 So if I place an autologous</p> <p>17 fascial sling or if I do a synthetic</p> <p>18 midurethral sling, the reimbursement is</p> <p>19 about the same. You know, Medicare data,</p> <p>20 with geographic area factors factored in,</p> <p>21 in this region, I would say probably the</p> <p>22 range is \$800 to, maybe, \$1,200 a</p> <p>23 procedure.</p> <p>24 Q. And how much would you be</p>	<p>1 placed in about 20 minutes.</p> <p>2 Q. And how about an autologous</p> <p>3 sling -- well, let me ask you this first:</p> <p>4 Are you performing any autologous sling</p> <p>5 procedures?</p> <p>6 A. In our practice, we don't</p> <p>7 currently perform autologous fascial</p> <p>8 slings in the last several years, because</p> <p>9 we reserve those for a certain subset of</p> <p>10 patients. And, fortunately, we've not</p> <p>11 had to go that far down the algorithm.</p> <p>12 Q. So it's been several years</p> <p>13 since you've placed an autologous -- or</p> <p>14 since you've performed an autologous --</p> <p>15 A. That's correct.</p> <p>16 Q. -- sling procedure?</p> <p>17 How about the last time you</p> <p>18 were -- performed a Burch procedure.</p> <p>19 A. The last time I performed a</p> <p>20 Burch procedure might be 2002.</p> <p>21 Q. But you were trained on both</p> <p>22 of those procedures, correct?</p> <p>23 A. Of course.</p> <p>24 Q. Do you teach residents and</p>

55 (Pages 214 to 217)

Marc Toggia, M.D.

Page 218	Page 220
<p>1 fellows?</p> <p>2 A. I do. I don't teach</p> <p>3 fellows, excuse me.</p> <p>4 Q. You teach residents?</p> <p>5 A. Correct.</p> <p>6 Q. At Thomas Jefferson?</p> <p>7 A. No. Lankenau Medical Center</p> <p>8 has an independent residency.</p> <p>9 Q. And I presume, since you're</p> <p>10 not performing a Burch or autologous</p> <p>11 sling, you're probably not teaching those</p> <p>12 to the residents currently?</p> <p>13 A. To be honest with you,</p> <p>14 excuse me, I'm sorry. I may have</p> <p>15 misspoke, as far as the last time I</p> <p>16 performed a Burch.</p> <p>17 When we're having this</p> <p>18 conversation, I'm thinking of standalone</p> <p>19 procedures. There may be combination</p> <p>20 procedures that we're doing it.</p> <p>21 I'll be very honest with</p> <p>22 you, I don't train -- the residents come</p> <p>23 to me for, really, basic training. We</p> <p>24 don't really train them to go on and</p>	<p>1 studies are important, yes, in how we</p> <p>2 practice medicine and how we -- how we</p> <p>3 make clinical decisions.</p> <p>4 Q. And it's important for</p> <p>5 patients so that they can give informed</p> <p>6 consent, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Some noncontroversial</p> <p>9 questions.</p> <p>10 And when you're looking at</p> <p>11 clinical studies, you want to see safety,</p> <p>12 correct?</p> <p>13 A. It depends upon the context</p> <p>14 of the study.</p> <p>15 Q. But in general, as a -- you</p> <p>16 know, broadly speaking you want to know</p> <p>17 the product is effective, correct?</p> <p>18 A. You know, again, within the</p> <p>19 context of that part of medicine that I</p> <p>20 practice as it pertains to surgery, we</p> <p>21 would phrase it, it's the balance between</p> <p>22 risk and benefit.</p> <p>23 Q. Okay. So you want</p> <p>24 studies --</p>
Page 219	Page 221
<p>1 independently perform a procedure like an</p> <p>2 autologous fascial sling or a Burch.</p> <p>3 They -- their role, in that kind of a</p> <p>4 setting, would be more observation or</p> <p>5 assistance.</p> <p>6 Q. Thanks. I know we talked a</p> <p>7 lot about studies, and I have a few</p> <p>8 questions that I want to ask you that I</p> <p>9 think will be relatively simple.</p> <p>10 And I know, from talking</p> <p>11 with you today, that you feel like</p> <p>12 clinical studies are important, correct?</p> <p>13 A. I think that levels of</p> <p>14 evidence are important.</p> <p>15 Q. And you've actually</p> <p>16 performed and published, including some</p> <p>17 randomized control trials, correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And they're -- you would</p> <p>20 agree with me that they are important so</p> <p>21 that doctors can make responsible</p> <p>22 treatment decisions, right?</p> <p>23 A. I think that, again, the</p> <p>24 levels of evidence provided by clinical</p>	<p>1 A. Surgery -- and safety, of</p> <p>2 course, would straddle risk and benefit.</p> <p>3 Q. I agree. And that's fine.</p> <p>4 A. And it's relative.</p> <p>5 Q. And I'm -- I'm happy to talk</p> <p>6 about to it -- talk it in terms of risk</p> <p>7 or complications and benefit or --</p> <p>8 A. Yes.</p> <p>9 Q. -- treatment success.</p> <p>10 And when you're looking at a</p> <p>11 study, regardless of the level, you want</p> <p>12 it to provide accurate information,</p> <p>13 correct?</p> <p>14 A. I'm not sure I understand</p> <p>15 what you're implying by the term</p> <p>16 "accurate."</p> <p>17 Q. You want the data that's</p> <p>18 presented to be correct? You want it to</p> <p>19 be -- what the study actually found is</p> <p>20 what you want to read when you're reading</p> <p>21 the publication, correct?</p> <p>22 MR. SNELL: Form.</p> <p>23 THE WITNESS: And I</p> <p>24 apologize, you know, I am an</p>

56 (Pages 218 to 221)

Marc Toggia, M.D.

Page 222	Page 224
<p>1 editor within this sphere, so --</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. So you're an editor of IUJ?</p> <p>4 A. Correct.</p> <p>5 Q. And also Female Pelvic</p> <p>6 Medicine; is that correct?</p> <p>7 A. And Reconstructive Surgery,</p> <p>8 it's one journal.</p> <p>9 Q. I just didn't want to say</p> <p>10 the whole thing, I'm getting tired.</p> <p>11 A. It took several decades to</p> <p>12 come up with that, so I do appreciate if</p> <p>13 you do say it.</p> <p>14 Q. Okay, I will --</p> <p>15 A. You can say FMPRS.</p> <p>16 Q. I will from now on.</p> <p>17 A. Thank you. I worked very</p> <p>18 hard for that, as you can imagine.</p> <p>19 Q. When did you last review an</p> <p>20 article or IUJ?</p> <p>21 A. It's within the last few</p> <p>22 weeks.</p> <p>23 Q. Was that a mesh article?</p> <p>24 A. The one in the last couple</p>	<p>1 manuscripts that relate to a particular</p> <p>2 center or individual's experience with a</p> <p>3 procedure. Oftentimes it's some variant</p> <p>4 of a procedure. And so, typically, it's</p> <p>5 looking at -- it's looking at that.</p> <p>6 Q. And you can't give -- be any</p> <p>7 more --</p> <p>8 A. Anti-incontinence procedure</p> <p>9 that involved some kind of mesh related</p> <p>10 material.</p> <p>11 And, again, I'm not giving</p> <p>12 you the name because it doesn't really</p> <p>13 have a name, it's something that they</p> <p>14 came up with themselves as an</p> <p>15 alternative.</p> <p>16 Q. Okay. And you want the</p> <p>17 studies that you look at to be objective,</p> <p>18 right?</p> <p>19 A. You and I can spend hours</p> <p>20 talking about whether anything is ever</p> <p>21 objective in this sphere. What we hope</p> <p>22 is that the studies are well defined,</p> <p>23 such that biases are apparent and that</p> <p>24 you minimize the unrecognized biases.</p>
Page 223	Page 225
<p>1 of weeks, I do not -- I know I've</p> <p>2 reviewed some mesh related articles</p> <p>3 within the past month, but the one in the</p> <p>4 last couple of weeks -- sometimes there's</p> <p>5 mesh involved, but that's not the primary</p> <p>6 objection, so --</p> <p>7 Q. Well, you would agree with</p> <p>8 me, as an editor --</p> <p>9 A. Excuse me. I'm sorry. I</p> <p>10 would say within the last three weeks,</p> <p>11 yes, I have reviewed an article primarily</p> <p>12 on mesh related procedures in this</p> <p>13 sphere.</p> <p>14 Q. And what was -- what was the</p> <p>15 gist of that article, if you can divulge</p> <p>16 it?</p> <p>17 A. So as you're well aware, the</p> <p>18 International Journal is an international</p> <p>19 journal, and so many of the submissions</p> <p>20 come from other countries. Many of the</p> <p>21 ones that I look at come either from the</p> <p>22 Middle East or China or one of the</p> <p>23 southeast, you know, Asian companies.</p> <p>24 Oftentimes we get</p>	<p>1 So, yes, we look at that.</p> <p>2 Q. So as objective as it can be</p> <p>3 under the constraints that it might have?</p> <p>4 A. And what goes along with</p> <p>5 that is that the -- that the endpoints,</p> <p>6 for example, are objective. You know,</p> <p>7 that these are not studies, say, for</p> <p>8 example, somebody picked up a telephone</p> <p>9 four years or five years later, called up</p> <p>10 patients and asked them a series of</p> <p>11 simple questions and then determined</p> <p>12 that -- determined the rate of success or</p> <p>13 not success based on that.</p> <p>14 You would prefer to have</p> <p>15 objective data.</p> <p>16 Q. Okay. So objective data, to</p> <p>17 the extent possible, you want to minimize</p> <p>18 bias or disclose bias, if it exists,</p> <p>19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. And you shouldn't decide</p> <p>22 what the results are going to be before</p> <p>23 you get the results, correct?</p> <p>24 A. You shouldn't, but that's</p>

57 (Pages 222 to 225)

Marc Toggia, M.D.

Page 226	Page 228
<p>1 often the case.</p> <p>2 Q. Would that cause you some</p> <p>3 concern if you reviewed a study, as an</p> <p>4 editor of one of those journals, that the</p> <p>5 results were predetermined?</p> <p>6 A. I think that's a</p> <p>7 different --</p> <p>8 MR. SNELL: Form.</p> <p>9 THE WITNESS: I'm sorry.</p> <p>10 I think that's different</p> <p>11 than what I just interpreted.</p> <p>12 I don't think -- no, I don't</p> <p>13 agree -- I don't agree that</p> <p>14 results are predetermined in the</p> <p>15 stuff that we look at. I think</p> <p>16 that there's always, you know --</p> <p>17 there's always a bias of what the</p> <p>18 results mean or what -- you know,</p> <p>19 what the results mean.</p> <p>20 So, yes, I mean, my -- my</p> <p>21 job, as an editor, is to read a</p> <p>22 study and to determine, did the</p> <p>23 study have a primary objective,</p> <p>24 did -- was the design sufficient</p>	<p>1 - - -</p> <p>2 (Whereupon, Exhibit</p> <p>3 Toggia-7, Bates ETH.MESH 05225354,</p> <p>4 05225380-384; TVT Instructions for</p> <p>5 Use, was marked for</p> <p>6 identification.)</p> <p>7 - - -</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. Dr. Toggia, have you seen</p> <p>10 this document from Ethicon before?</p> <p>11 MR. SNELL: I'm going to</p> <p>12 object. This is part of a larger</p> <p>13 document that has been provided.</p> <p>14 You're just cutting two pages.</p> <p>15 MS. THOMPSON: And we can</p> <p>16 get the larger document, if you</p> <p>17 want him to have it for this</p> <p>18 purpose.</p> <p>19 MR. SNELL: I'm sure it's</p> <p>20 here somewhere in the files.</p> <p>21 MS. THOMPSON: Okay. If you</p> <p>22 want him to see it, you're welcome</p> <p>23 to pull it out.</p> <p>24 THE WITNESS: Again, I mean,</p>
Page 227	Page 229
<p>1 that they could comment on that</p> <p>2 objective; and, more importantly,</p> <p>3 when looking at the results, do</p> <p>4 they accurately interpret the</p> <p>5 significance of those results.</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. What would you do if you</p> <p>8 were an editor and received a paper where</p> <p>9 the results were predetermined?</p> <p>10 MR. SNELL: Form.</p> <p>11 Incomplete --</p> <p>12 THE WITNESS: I don't</p> <p>13 know -- I don't understand --</p> <p>14 MR. SNELL: -- hypothetical.</p> <p>15 MS. THOMPSON: Sorry?</p> <p>16 THE WITNESS: -- how I would</p> <p>17 know they were predetermined.</p> <p>18 MR. SNELL: Incomplete</p> <p>19 hypothetical.</p> <p>20 MS. THOMPSON: I'm going to</p> <p>21 give you -- --</p> <p>22 THE WITNESS: If the results</p> <p>23 are predetermined, you wouldn't</p> <p>24 need a study.</p>	<p>1 I'm not -- I don't know --</p> <p>2 understand the context of what</p> <p>3 this is describing. I'm familiar</p> <p>4 with the --</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. Well, let me ask you this:</p> <p>7 Dr. Toggia --</p> <p>8 A. Yes.</p> <p>9 Q. -- did you see the contract</p> <p>10 with -- between Ethicon and Drs. Olmstead</p> <p>11 and Nielsen?</p> <p>12 MR. SNELL: Hold on.</p> <p>13 Objection. Foundation and form.</p> <p>14 And that actually misstates the</p> <p>15 evidence.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: I believe that</p> <p>18 that's outside the sphere of the</p> <p>19 task that I was given to look at</p> <p>20 the design and the safety of the</p> <p>21 TVT device.</p> <p>22 BY MS. THOMPSON:</p> <p>23 Q. I believe Dr. -- Mr. Snell</p> <p>24 said that you had this -- the contract</p>

58 (Pages 226 to 229)

Marc Toggia, M.D.

Page 230	Page 232
<p>1 that this is the attachment to.</p> <p>2 A. I'm not -- I'm not telling</p> <p>3 you that I'm not familiar with this</p> <p>4 document or that I may not have perused</p> <p>5 this document.</p> <p>6 However, I may not have -- I</p> <p>7 may not have committed to memory, you</p> <p>8 know, the details of these things.</p> <p>9 I mean, I've looked at</p> <p>10 thousands of things.</p> <p>11 Q. Let's read through it.</p> <p>12 A. But for intents and</p> <p>13 purposes, you know, I would not say that</p> <p>14 I could speak to the details of what you</p> <p>15 presented to me.</p> <p>16 Q. So you're not giving</p> <p>17 opinions as to the Olmstead studies</p> <p>18 regarding TVT?</p> <p>19 MR. SNELL: Actually,</p> <p>20 objection.</p> <p>21 THE WITNESS: I think I've</p> <p>22 given opinions within my expert</p> <p>23 reports. I'd be happy to pause</p> <p>24 and point them out to you, if</p>	<p>1 interpretation of what we're</p> <p>2 looking at here?</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. No, you don't need to give</p> <p>5 me your interpretation. I'll ask you --</p> <p>6 A. You've asked me about this</p> <p>7 document.</p> <p>8 Q. -- you a question and you</p> <p>9 can answer it.</p> <p>10 So if the investigators were</p> <p>11 only paid if these objectives were met,</p> <p>12 would that be an appropriate design for a</p> <p>13 clinical study?</p> <p>14 MR. SNELL: Objection to</p> <p>15 form.</p> <p>16 MS. THOMPSON: That's a</p> <p>17 hypothetical.</p> <p>18 THE WITNESS: Yes, I</p> <p>19 understand. My -- let's make sure</p> <p>20 we're talking about the same</p> <p>21 studies.</p> <p>22 My understanding is that</p> <p>23 this is referring to the</p> <p>24 multicenter studies on the TVT</p>
Page 231	Page 233
<p>1 you'd like, counselor.</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. I guess I just misunderstood</p> <p>4 your answer.</p> <p>5 A. Yes.</p> <p>6 Q. Let me -- let me just -- so</p> <p>7 this exhibit states, The results of the</p> <p>8 clinical trials will be considered</p> <p>9 acceptable if, first, they do not differ</p> <p>10 significantly from the results published</p> <p>11 in the original article.</p> <p>12 To you, is that an</p> <p>13 appropriate study design?</p> <p>14 MR. SNELL: Objection.</p> <p>15 Misstates. Form.</p> <p>16 THE WITNESS: This doesn't</p> <p>17 refer to that, counselor. This is</p> <p>18 not -- I mean, this is not saying</p> <p>19 that it's acceptable to -- for</p> <p>20 publication, that -- this</p> <p>21 doesn't -- I mean, the fact that</p> <p>22 it speaks to the results has</p> <p>23 nothing to do with the design.</p> <p>24 I -- may I give you my</p>	<p>1 device and that Olmstead did</p> <p>2 not -- was not a participating</p> <p>3 site in the multicenter study.</p> <p>4 But Olmstead was the individual</p> <p>5 becoming -- who was being paid.</p> <p>6 Am I correct?</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. Who told you that? Or where</p> <p>9 did you come up with that?</p> <p>10 A. Nobody told me that. That</p> <p>11 was just -- I'm just asking you, that was</p> <p>12 kind of my -- that's kind of where I'm</p> <p>13 coming from.</p> <p>14 Can you show me the specific</p> <p>15 study that we're referring to here?</p> <p>16 Q. Mr. Snell -- I'm just asking</p> <p>17 you about this contract.</p> <p>18 A. I'm asking you whether you</p> <p>19 can show me -- I don't know what this is</p> <p>20 connected to, what study this is</p> <p>21 connected to.</p> <p>22 Q. There have been multiple</p> <p>23 studies that have been published --</p> <p>24 A. Right.</p>

59 (Pages 230 to 233)

Marc Toggia, M.D.

Page 234	Page 236
<p>1 Q. -- from the original 2 cohort -- 3 A. Right. 4 Q. -- correct? 5 MR. SNELL: Objection. 6 Form. Vague. 7 THE WITNESS: I will answer 8 that question. 9 The original -- I don't 10 know -- the original Olmstead 11 study involved, I think, roughly 12 about 50 patients. I don't -- I'm 13 aware of the longitudinal studies 14 where Nielsen published on the 15 same cohort of patients at a year, 16 two years, five years, seven 17 years, you know, ten years, et 18 cetera, twelve years, et cetera, 19 et cetera, so on, 11.5 years, 17 20 years. 21 That's not -- I'm just 22 clarifying. That's not the same 23 as Olmstead. Olmstead's original 24 report was a series of, I think,</p>	<p>1 trying to understand his answer. 2 THE WITNESS: No, no, I 3 understand. 4 And, counselor, I understand 5 that you are -- here is my problem 6 and my confusion, okay? You are, 7 at the same time, asking me a very 8 general question about things I do 9 as an editor in science in 10 general. 11 At the same time, you're 12 putting a very specific document, 13 in isolation, and not providing me 14 with the reference study and 15 you're asking me to make a comment 16 in the middle that seems to link 17 one with the other. 18 And I'm telling you, I'm not 19 able to -- I don't know how -- not 20 that I'm -- not that I'm will -- 21 I'm not willing to, I don't know 22 how to make an answer about a 23 study that I don't know -- don't 24 know anything about.</p>
Page 235	Page 237
<p>1 roughly 50 patients that he 2 himself operated on. 3 And I don't believe that 4 this document refers back to that 5 original study. 6 BY MS. THOMPSON: 7 Q. Is this -- is it an 8 appropriate study design where the 9 investigator is paid if certain criteria 10 are met when the results are published? 11 MR. SNELL: Objection to 12 form. Misstates the evidence. 13 THE WITNESS: I don't -- 14 MR. SNELL: Asked and 15 answered. 16 THE WITNESS: I don't know 17 how to answer that. I'm sorry. 18 BY MS. THOMPSON: 19 Q. So you don't know how to 20 answer a question about you're only going 21 to get paid if you get these results? 22 MR. SNELL: Hold on. 23 Objection. Argumentative. 24 MS. THOMPSON: I'm just</p>	<p>1 BY MS. THOMPSON: 2 Q. I'm only talking about the 3 design of a study. 4 Is this an appropriate 5 design of a study? 6 MR. SNELL: Objection to 7 form. 8 THE WITNESS: This paper 9 does not address a design of the 10 study. This paper does not 11 stipulate if the study is not 12 designed to our satisfaction, 13 they'll be no reimbursement. This 14 study speaks to results. 15 BY MS. THOMPSON: 16 Q. Okay. We'll move on. 17 A. And the results have nothing 18 to do with the design. Nor do I see a 19 phrase that says, the study has to be 20 designed such that these results must 21 be -- 22 Q. No. It's just the 23 investigator wasn't paid if the results 24 weren't -- weren't met.</p>

60 (Pages 234 to 237)

Marc Toggia, M.D.

<p style="text-align: right;">Page 238</p> <p>1 MR. SNELL: Objection. Move</p> <p>2 to strike.</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Were you shown -- prior to</p> <p>5 working in this lawsuit, were you shown</p> <p>6 the material safety data sheet related to</p> <p>7 the polypropylene used in Ethicon mesh</p> <p>8 devices? And you're a chemist, you know</p> <p>9 what a material safety data sheet is --</p> <p>10 A. I do.</p> <p>11 Q. -- correct?</p> <p>12 A. I do.</p> <p>13 No. I did not -- I did not</p> <p>14 previously look at that material.</p> <p>15 - - -</p> <p>16 (Whereupon, Exhibit</p> <p>17 Toggia-8, ETH.MESH 08696131-132,</p> <p>18 Exhibit C - Clinical Trials, was</p> <p>19 marked for identification.)</p> <p>20 - - -</p> <p>21 THE WITNESS: We're talking</p> <p>22 specifically about regulatory</p> <p>23 paperwork. This is non-clinical</p> <p>24 regulatory type stuff.</p>	<p style="text-align: right;">Page 240</p> <p>1 calcium hypochlorite, permanganates,</p> <p>2 chlorine and nitric acid.</p> <p>3 Q. And are those compounds</p> <p>4 found in the human body?</p> <p>5 A. Within the context of this</p> <p>6 type of testing, I would say they are</p> <p>7 probably not. And I don't see -- I don't</p> <p>8 see anything that says that -- that</p> <p>9 references in concentrations normally</p> <p>10 found within human tissue.</p> <p>11 Q. And under Number 15, other</p> <p>12 information --</p> <p>13 A. Yes.</p> <p>14 Q. -- component toxicity, could</p> <p>15 you read the sentences after that?</p> <p>16 A. Sure. Polypropylene has</p> <p>17 been tested in laboratory rats by</p> <p>18 subcutaneous implants of disc or powder.</p> <p>19 Local sarcomas were induced at the site</p> <p>20 of implantation. No epidemiologic</p> <p>21 studies or case reports suggest any</p> <p>22 serious chronic health hazards from</p> <p>23 long-term exposure to polypropylene</p> <p>24 decomposition products below the</p>
<p style="text-align: right;">Page 239</p> <p>1 MS. THOMPSON: I don't think</p> <p>2 there was a question pending, but</p> <p>3 I don't think -- sorry. I don't</p> <p>4 think the material safety data</p> <p>5 sheet is a regulatory document.</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. Okay. Have you seen the</p> <p>8 material safety data sheet now, since</p> <p>9 you've been working on this lawsuit?</p> <p>10 A. Yes. This was part of</p> <p>11 the -- this was part of the materials</p> <p>12 provided to me.</p> <p>13 Q. And I'll direct your</p> <p>14 attention to Number 10 in the material</p> <p>15 safety data sheet regarding stability and</p> <p>16 reactivity.</p> <p>17 A. Yes.</p> <p>18 Q. Could you read the sentences</p> <p>19 under incompatibility?</p> <p>20 A. The following materials are</p> <p>21 incompatible with this product. Strong</p> <p>22 oxidizers, such as chlorine, peroxides,</p> <p>23 chromates, nitric acid, perchlorates,</p> <p>24 concentrated oxygen, sodium hypochlorite,</p>	<p style="text-align: right;">Page 241</p> <p>1 irritation level.</p> <p>2 Q. Did Ethicon perform any</p> <p>3 studies to determine whether or not the</p> <p>4 polypropylene used in their mesh devices</p> <p>5 causes sarcoma in humans?</p> <p>6 A. I don't see that -- that</p> <p>7 discs of polypropylene or powders of</p> <p>8 polypropylene have anything to do with</p> <p>9 the TVT device when used for its proper</p> <p>10 indication of stress incontinence in</p> <p>11 women.</p> <p>12 I think that the science in</p> <p>13 this area, it is well known that the</p> <p>14 formation of sarcoma is related to form,</p> <p>15 form material, and that you can't</p> <p>16 extrapolate from laboratory rats to</p> <p>17 humans.</p> <p>18 Q. So the answer is you're not</p> <p>19 aware of any studies that Ethicon did to</p> <p>20 determine whether a TVT mesh could lead</p> <p>21 to sarcoma?</p> <p>22 A. Let me just refer to my</p> <p>23 report for a second.</p> <p>24 I think it's fair to say</p>

61 (Pages 238 to 241)

Marc Toggia, M.D.

<p style="text-align: right;">Page 242</p> <p>1 that they did not, but I don't see -- I</p> <p>2 wouldn't understand why that would be --</p> <p>3 why that would be relevant.</p> <p>4 Q. Is this information</p> <p>5 something you would want to know, as a</p> <p>6 physician?</p> <p>7 MR. SNELL: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Maybe if I was</p> <p>10 a veterinarian caring for rats and</p> <p>11 I was implanting discs or powders.</p> <p>12 But this information is not</p> <p>13 pertinent or clinically relevant.</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. Is this information about</p> <p>16 the polypropylene used in the Ethicon</p> <p>17 pelvic mesh products something that</p> <p>18 patients should be informed of?</p> <p>19 MR. SNELL: Same objection.</p> <p>20 THE WITNESS: To the best of</p> <p>21 my knowledge, polypropylene discs</p> <p>22 or powders are not used in the TVT</p> <p>23 product. And at the same time,</p> <p>24 the TVT product is not used in</p>	<p style="text-align: right;">Page 244</p> <p>1 a human for 30 years?</p> <p>2 A. If the first clinical trials</p> <p>3 of a TVT were published somewhere around</p> <p>4 '96, we would be 20 years. Did I do that</p> <p>5 wrong? I was thinking '86.</p> <p>6 We are probably a few --</p> <p>7 we're probably a few years shy of that.</p> <p>8 Q. All right. I'm going to ask</p> <p>9 you about whether or not you had seen any</p> <p>10 documents or whether Ethicon had told you</p> <p>11 about certain things prior to your</p> <p>12 involvement in this lawsuit, okay?</p> <p>13 A. Okay.</p> <p>14 Q. Is that -- do you</p> <p>15 understand?</p> <p>16 MR. SNELL: Can I say one</p> <p>17 thing? Off the record.</p> <p>18 VIDEO TECHNICIAN: We are</p> <p>19 off the record. The time is 6:04</p> <p>20 p.m.</p> <p>21 - - -</p> <p>22 (Whereupon, a brief recess</p> <p>23 was taken.)</p> <p>24 - - -</p>
<p style="text-align: right;">Page 243</p> <p>1 rats.</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. But the fact that the disc</p> <p>4 and powder in rats may cause cancer is</p> <p>5 irrelevant, in your opinion?</p> <p>6 A. I think animal studies have</p> <p>7 established that -- that it's related to</p> <p>8 both the -- the animal and the form and</p> <p>9 that it is not transferable to humans.</p> <p>10 Q. Are you familiar with the</p> <p>11 term "latency period"?</p> <p>12 A. Yes.</p> <p>13 Q. Do you know what the latency</p> <p>14 period for exposure and development of</p> <p>15 sarcoma is thought to be in humans?</p> <p>16 A. No, I'm not.</p> <p>17 Q. Would it surprise you if</p> <p>18 it's 30 years?</p> <p>19 MR. SNELL: Form. Vague.</p> <p>20 Lacks foundation.</p> <p>21 THE WITNESS: It probably</p> <p>22 would surprise me, yes.</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Has a TVT been implanted in</p>	<p style="text-align: right;">Page 245</p> <p>1 VIDEO TECHNICIAN: This</p> <p>2 marks the beginning of Video</p> <p>3 Number 4. We are back on the</p> <p>4 record. The time is 6:06 p.m.</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. So, Dr. Toggia, I'm going to</p> <p>7 ask you some questions about whether you</p> <p>8 either saw documents or Ethicon told you</p> <p>9 about certain things. And this would all</p> <p>10 be prior to your involvement in this</p> <p>11 lawsuit.</p> <p>12 A. Yes.</p> <p>13 Q. Did Ethicon tell you that</p> <p>14 mechanically cut mesh thins or stretches</p> <p>15 when it's placed under tension?</p> <p>16 MR. SNELL: Form.</p> <p>17 THE WITNESS: I don't need</p> <p>18 Ethicon to tell me about the</p> <p>19 properties of the material, given</p> <p>20 that I handle it on a frequent</p> <p>21 basis.</p> <p>22 BY MS. THOMPSON:</p> <p>23 Q. And other doctors don't need</p> <p>24 that information either?</p>

62 (Pages 242 to 245)

Marc Toggia, M.D.

Page 246	Page 248
<p>1 A. I'm sorry, I don't see the</p> <p>2 relationship to that -- the question.</p> <p>3 Q. Is it your opinion that</p> <p>4 doctors generally don't need the</p> <p>5 information that Ethicon has about the</p> <p>6 mechanically cut mesh thinning --</p> <p>7 A. All right.</p> <p>8 Q. -- and stretching on</p> <p>9 tension?</p> <p>10 A. So we're no longer talking</p> <p>11 about what you said that we're going to</p> <p>12 talk about, which was Ethicon's</p> <p>13 communication with me on this material?</p> <p>14 Are we done with that?</p> <p>15 Q. Well, on this particular</p> <p>16 item, I want to know whether you think --</p> <p>17 you said it's not -- you don't need to</p> <p>18 hear it from Ethicon.</p> <p>19 A. Correct.</p> <p>20 Q. I'm asking you, do other</p> <p>21 doctors need to hear it or would want to</p> <p>22 hear it from Ethicon?</p> <p>23 MR. SNELL: Form.</p> <p>24 THE WITNESS: I don't</p>	<p>1 THE WITNESS: Again, I don't</p> <p>2 rely upon Ethicon to tell -- to</p> <p>3 provide me with information as it</p> <p>4 relates to how I manage patients</p> <p>5 or the materials that I use.</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. And you're not -- you do not</p> <p>8 feel like you can give an opinion as to</p> <p>9 whether other doctors would want to or</p> <p>10 need that information?</p> <p>11 A. I think that's beyond the</p> <p>12 scope of what I've prepared, yes.</p> <p>13 Q. Okay. Did Ethicon, and</p> <p>14 there are going to be a whole bunch of</p> <p>15 these, so if your answer is the same we</p> <p>16 can kind of go with that.</p> <p>17 A. I don't know what you're</p> <p>18 going to ask me.</p> <p>19 Q. Did Ethicon tell you or show</p> <p>20 you documents showing fraying of</p> <p>21 mechanically cut mesh?</p> <p>22 MR. SNELL: Form.</p> <p>23 Go ahead.</p> <p>24 THE WITNESS: I've seen</p>
Page 247	Page 249
<p>1 know -- I don't know what other</p> <p>2 doctors would need or want to</p> <p>3 hear. I think that, you know, in</p> <p>4 the -- prior to my involvement in</p> <p>5 this matter, there were</p> <p>6 discussions amongst physicians and</p> <p>7 Ethicon engineers, and other</p> <p>8 people, where we discussed the</p> <p>9 properties of mechanically cut</p> <p>10 mesh and how it behaves under both</p> <p>11 physiologic and nonphysiologic,</p> <p>12 you know, circumstances.</p> <p>13 I would say, again, as a</p> <p>14 surgeon, the nonphysiologic stuff</p> <p>15 really is of no clinical meaning,</p> <p>16 nor do I think that you can infer</p> <p>17 any kind of clinical importance to</p> <p>18 that information.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Okay. And even if Ethicon</p> <p>21 thought it was clinically important, you</p> <p>22 didn't feel like you needed to have that</p> <p>23 information?</p> <p>24 MR. SNELL: Form.</p>	<p>1 documents that -- I don't know</p> <p>2 that I would use the word</p> <p>3 "fraying," per se. I think you're</p> <p>4 implying, you know -- or labeling,</p> <p>5 per se.</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. You've never seen documents</p> <p>8 that use the word "fraying"?</p> <p>9 A. No, there are documents that</p> <p>10 use the word "fraying."</p> <p>11 Q. Ethicon documents?</p> <p>12 A. There are Ethicon documents</p> <p>13 that use the word "fraying." I have seen</p> <p>14 those documents.</p> <p>15 Q. So, at least, people at</p> <p>16 Ethicon called it fraying?</p> <p>17 A. Yeah. I just -- I just --</p> <p>18 what's the working definition of fraying?</p> <p>19 Is your definition of fraying the same as</p> <p>20 mine? The same as theirs?</p> <p>21 Q. But is that the same, in</p> <p>22 your opinion, that that -- that</p> <p>23 information is irrelevant to you in your</p> <p>24 practice?</p>

63 (Pages 246 to 249)

Marc Toggia, M.D.

Page 250	Page 252
<p>1 A. No. I don't think that's</p> <p>2 what I'm speaking to. Information is</p> <p>3 relevant. Whether it's relevant that</p> <p>4 Ethicon absolutely had to communicate</p> <p>5 one-on-one with me on that particular</p> <p>6 issue is what I'm speaking about.</p> <p>7 Q. I don't -- I don't think I</p> <p>8 asked about one-on-one.</p> <p>9 I'm just asking you, is that</p> <p>10 information that you would have liked to</p> <p>11 have known, if Ethicon had that</p> <p>12 information?</p> <p>13 A. I did know about that</p> <p>14 information, and I did receive that</p> <p>15 information from Ethicon.</p> <p>16 Q. Okay. And did other doctors</p> <p>17 receive that information --</p> <p>18 A. Yes.</p> <p>19 Q. -- that mechanically cut</p> <p>20 mesh frayed?</p> <p>21 A. Yes.</p> <p>22 Q. Did you teach about that</p> <p>23 when you were doing your courses or doing</p> <p>24 your preceptor training?</p>	<p>1 Q. So if Ethicon thought --</p> <p>2 Ethicon thought they were using</p> <p>3 physiologically forces, you would</p> <p>4 disagree with them?</p> <p>5 A. I'm sorry?</p> <p>6 Q. If Ethicon, when they did</p> <p>7 their testing, stated that they were</p> <p>8 using physiologic circumstances, you</p> <p>9 would disagree with them?</p> <p>10 MR. SNELL: Objection to</p> <p>11 form. Vague.</p> <p>12 THE WITNESS: I would</p> <p>13 disagree that they were using</p> <p>14 phys --</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. The amount of stretch, for</p> <p>17 example? The tension applied, for</p> <p>18 example?</p> <p>19 A. I mean, the only --</p> <p>20 MR. SNELL: Same objection.</p> <p>21 THE WITNESS: I can answer</p> <p>22 it like this: I am aware that</p> <p>23 Ethicon conducted testing looking</p> <p>24 at the mechanical properties of</p>
Page 251	Page 253
<p>1 A. Well, again, the fraying</p> <p>2 occurred at nonphysiologic, you know,</p> <p>3 forces. And so, yes, I think that we did</p> <p>4 talk about mesh, its properties, its</p> <p>5 behavior, how the -- how -- why it was</p> <p>6 important to adhere to the well-described</p> <p>7 steps of the procedure in order for the</p> <p>8 mesh to perform with -- under the normal</p> <p>9 physiologic load, under the normal</p> <p>10 physiologic capacity, and in that</p> <p>11 capacity, fraying was not a clinical</p> <p>12 concern.</p> <p>13 Q. Who told you that these were</p> <p>14 nonphysiologic forces?</p> <p>15 A. Based upon, you know, my</p> <p>16 body of knowledge, reading the material,</p> <p>17 discussing with other experts, you know,</p> <p>18 having to do a little bit of reading</p> <p>19 about physiologic forces.</p> <p>20 I mean, physiologic forces</p> <p>21 within the pelvic floor, obviously, is</p> <p>22 somewhat unique to our subspecialty. I</p> <p>23 don't expect that people are taught that</p> <p>24 in medical school, for example.</p>	<p>1 the mesh and that that testing</p> <p>2 started from no -- you know, no</p> <p>3 tension through the physiologic</p> <p>4 range to supraphysiologic range.</p> <p>5 It was looked -- it was</p> <p>6 looked upon -- and this is all</p> <p>7 kind of -- how the material</p> <p>8 behaves in that regard, to be</p> <p>9 honest with you, has very little</p> <p>10 to do with how the material</p> <p>11 behaves once it's incorporated or</p> <p>12 placed within the body.</p> <p>13 But I know that -- I know</p> <p>14 that they did perform those tests.</p> <p>15 I've seen the results of those</p> <p>16 tests. We have probably, in the</p> <p>17 past, spoken about data that talks</p> <p>18 about the different meshes, are</p> <p>19 they similar -- are they</p> <p>20 different, similar, physiologic</p> <p>21 load, supraphysiologic load.</p> <p>22 Those were all fairly freely</p> <p>23 discussed.</p> <p>24 BY MS. THOMPSON:</p>

64 (Pages 250 to 253)

Marc Toggia, M.D.

Page 254	Page 256
<p>1 Q. What about roping or curling 2 of the TVT mesh, was that something that 3 was discussed with you prior to your 4 involvement in this lawsuit?</p> <p>5 A. Well, I can -- again, I can 6 tell you, from using that mechanically -- 7 mesh for an extended period of time, you 8 know, the mesh does not rope or curl when 9 it's -- when -- you know, in the context 10 that it has a -- the protective sheath 11 over it. And we don't place the mesh 12 without the protective sheath.</p> <p>13 When the meth -- so when 14 you're delivering the mesh in the TVT 15 procedure, the sheath is carrying the 16 mesh. The mesh is passive. The mesh is 17 not exposed to the those forces. It's 18 only after the sheath is positioned that 19 you pull the mesh off. Somewhat like the 20 magic trick where you kind of -- not that 21 it's a magic trick, where you pull the 22 table cloth and the stack of cups goes 23 undisturbed.</p> <p>24 The mesh is never, in the</p>	<p>1 Q. And would that be the same 2 for other physicians as well?</p> <p>3 A. I can't speak to what other 4 physicians might consider to be relevant.</p> <p>5 Q. If Ethicon had information 6 that the fraying, roping and curling 7 actually increased the risk of retention, 8 is that information that you would like 9 to have?</p> <p>10 A. I -- I would --</p> <p>11 MR. SNELL: Form. 12 Foundation.</p> <p>13 THE WITNESS: -- say that I 14 know that information independent 15 of that -- I don't need that 16 information -- okay, Ethicon does 17 not implant these meshes in women. 18 I implant these meshes in women. 19 I implant these meshes in over 100 20 women a year for the past 17 21 years. I am well aware of how 22 this particular material behaves 23 within the body, and I can tell 24 you, when it is done properly,</p>
Page 255	Page 257
<p>1 clinical application of the TVT, as we 2 use it, as I use it for stress 3 incontinence, we don't apply any 4 physiologic force.</p> <p>5 The only -- the only thing 6 that I would say is that you've got 7 minimal static and rolling friction that 8 does occur as you remove the sheath and 9 the mesh is left behind.</p> <p>10 Q. So your -- your testimony is 11 that the mesh, if it is placed flat, 12 remains flat?</p> <p>13 A. Correct.</p> <p>14 Q. And if Ethicon had evidence 15 to the contrary, is that something that 16 you would like to know about?</p> <p>17 MR. SNELL: Form. 18 Go ahead.</p> <p>19 THE WITNESS: It wouldn't 20 hurt my feelings if I was not 21 aware of that information. I 22 don't see how that information is 23 clinically relevant in my world.</p> <p>24 BY MS. THOMPSON:</p>	<p>1 there is no roping, there is no 2 curling.</p> <p>3 BY MS. THOMPSON: 4 Q. And is that information that 5 other physicians would -- would want to 6 know or need to know from Ethicon?</p> <p>7 MR. SNELL: Form.</p> <p>8 THE WITNESS: I would say 9 within the context of the 10 instructions for use, which 11 outlined, in great detail, the 12 very specific steps that are to be 13 taken, when performed in that 14 manner, there is no roping or 15 curling of the material.</p> <p>16 And keep in mind, we're 17 talking about the tension-free 18 placement of the mesh. So that 19 excludes --</p> <p>20 BY MS. THOMPSON: 21 Q. And you'll agree -- 22 A. So that excludes all of the 23 testing that you are referring to, 24 because all those testing refer to</p>

65 (Pages 254 to 257)

Marc Toggia, M.D.

Page 258	Page 260
<p>1 tension, whether it's physiologic or</p> <p>2 nonphysiologic.</p> <p>3 Q. You'll agree with me that</p> <p>4 the mesh shrinks, contracts?</p> <p>5 MR. SNELL: Form.</p> <p>6 Overbroad.</p> <p>7 THE WITNESS: As a general</p> <p>8 sense, a hernia mesh, there is</p> <p>9 shrinkage. Whether there is</p> <p>10 shrinkage in a TVT mesh, I don't</p> <p>11 believe that there is clinically</p> <p>12 significant shrinkage.</p> <p>13 Now, of course, because this</p> <p>14 is the most highly biocompatible</p> <p>15 mesh there is, it allows for the</p> <p>16 ingrowth of fibroblasts and</p> <p>17 reticulocytes. It allows for the</p> <p>18 infiltration of white cells and</p> <p>19 angiogenesis.</p> <p>20 As the tissue heals against</p> <p>21 the mesh, the mesh is going to</p> <p>22 change, and that is expected. And</p> <p>23 that was actually the -- the</p> <p>24 original design of the TVT</p>	<p>1 stating otherwise?</p> <p>2 MR. SNELL: Objection to</p> <p>3 form. Misstates the evidence.</p> <p>4 THE WITNESS: My opinion, as</p> <p>5 an expert, the TVT mesh is Type I,</p> <p>6 regardless of Ethicon were to tell</p> <p>7 me yes or no.</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. Okay. If Ethicon had</p> <p>10 information that showed that the fraying,</p> <p>11 roping and curling causes the pores to</p> <p>12 collapse or close and render the mesh no</p> <p>13 longer macroporous, is that information</p> <p>14 that you would like to know about?</p> <p>15 MR. SNELL: Form.</p> <p>16 Foundation.</p> <p>17 THE WITNESS: I don't see</p> <p>18 how it's relevant, counselor,</p> <p>19 okay?</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. That's -- that's a perfectly</p> <p>22 acceptable answer.</p> <p>23 A. As a surgeon, is it -- is it</p> <p>24 effective.</p>
Page 259	Page 261
<p>1 specifically spoke to the fact</p> <p>2 that the mesh would -- the mesh</p> <p>3 would induce collagen formation</p> <p>4 and other structural changes in</p> <p>5 the area around the mesh. And</p> <p>6 that was considered to be an</p> <p>7 important part of the clinical</p> <p>8 effect.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. What's your basis for saying</p> <p>11 TVT is the most highly biocompatible mesh</p> <p>12 there is?</p> <p>13 A. I'm sorry. Macroporous</p> <p>14 polypropylene mesh that is classified as</p> <p>15 Type I by the Amid classification. Of</p> <p>16 which --</p> <p>17 Q. And that's what --</p> <p>18 A. -- of which --</p> <p>19 Q. -- you believe TVT is?</p> <p>20 A. Of which TVT has been the</p> <p>21 most extensively studied.</p> <p>22 Q. And you believe that it is?</p> <p>23 A. I know it is, yes.</p> <p>24 Q. Despite Ethicon documents</p>	<p>1 Q. If Ethicon -- and that goes</p> <p>2 the same for other doctors as well?</p> <p>3 A. I can't speak to what other</p> <p>4 doctors might hold to be important or</p> <p>5 what they might comment.</p> <p>6 Q. If Ethicon has information</p> <p>7 that fraying, roping and curling of their</p> <p>8 mesh leads to an increased risk of</p> <p>9 erosion, is that information that you</p> <p>10 would like to have?</p> <p>11 MR. SNELL: Form.</p> <p>12 Foundation.</p> <p>13 THE WITNESS: I can tell you</p> <p>14 I have an independent opinion</p> <p>15 that, yes, if the mesh were to</p> <p>16 curl, that there might be an</p> <p>17 increased risk of erosion relative</p> <p>18 to a mesh that has not curled.</p> <p>19 Now, the risk of exposure</p> <p>20 might go from, say, .6 to .7</p> <p>21 percent, which is what it has been</p> <p>22 in most clinical trials; maybe</p> <p>23 that might go up to, say, 1.2, 3</p> <p>24 percent, 3.2 percent.</p>

66 (Pages 258 to 261)

Marc Toggia, M.D.

Page 262	Page 264
<p>1 But I would agree -- I mean, 2 I would say I have had the same 3 observation, and I don't need to 4 hear that from Ethicon, that if 5 the mesh is not placed in a 6 tension-free manner -- the mesh is 7 not going to rope or curl if it's 8 tension free. Because in it's 9 native state, the mesh is not 10 roped or curled. 11 BY MS. THOMPSON: 12 Q. And I think you've already 13 stated that if it's placed flat, in your 14 opinion, it remains flat? 15 A. That's correct. 16 Q. If Ethicon had information 17 that fraying and roping and curling of 18 mechanically cut mesh leads to an 19 increased risk of bridging fibrosis, is 20 that information you would want to have? 21 MR. SNELL: Form. 22 THE WITNESS: I would -- 23 again, bridging fibrosis, in my 24 opinion, is likely to be a natural</p>	<p>1 All surgical procedures result 2 some scarring. 3 Now, whether those -- that 4 scarring occurs from the incision 5 that I've made, whether it occurs 6 from the suture that I've placed, 7 whether it occurs based upon 8 something else I may do, I don't 9 know how I would separate, you 10 know, one from the other. 11 You can -- you will never 12 have no scarring, despite what the 13 TV ads will say. There's no 14 scarless surgery. 15 BY MS. THOMPSON: 16 Q. Do you use polypropylene 17 suture in the vagina? 18 A. Yes. 19 Q. For what procedure? 20 A. Again, the vast majority of 21 what I do in the reconstructive world 22 involves some -- some formulation of 23 polypropylene. Polypropylene sutures are 24 commonly used in all of urogynecology for</p>
Page 263	Page 265
<p>1 or an expected outcome. It's, 2 again, speaking to what the 3 original design -- it was hoped 4 that there would be the induction 5 of collagen, mature collagen 6 formation. 7 And that, yes, I mean, all 8 of these procedures, in the -- in 9 the world of prolapse 10 incontinence, you're kind of 11 hoping that there's a certain 12 degree, again, within a 13 physiologic range, that there's 14 fibrosis, that occurs, absolutely. 15 BY MS. THOMPSON: 16 Q. In other words, replace with 17 scar? 18 MR. SNELL: Form. 19 THE WITNESS: I don't know 20 how it is that you're interpreting 21 scar. I'm talking about the -- 22 you want it to induce a certain 23 amount of collagen formation; in a 24 very loose sense scarring, sure.</p>	<p>1 apical vaginal suspensions. 2 Q. When you place a 3 polypropylene suture, how much suture is 4 left in the body? What's the length of 5 suture? 6 A. I would say that the length 7 of suture left behind, understanding 8 that, obviously, we've tied a series of 9 knots, I don't know if you're -- you just 10 want -- I mean, the whole thing, in 11 aggregate, is less than a centimeter. 12 If I were to unwind or untie 13 it and stretch it out, that could be, 14 maybe, 3 centimeters. But I don't think 15 that's an accurate -- accurate 16 description. I would say, in general, 17 it's half a centimeter to a centimeter. 18 Q. And do you have any idea how 19 much -- what the length of suture with 20 filaments would be if you stretched out 21 all the polypropylene in a TVT? 22 MR. SNELL: Objection to 23 form. 24 THE WITNESS: I don't have</p>

67 (Pages 262 to 265)

Marc Toggia, M.D.

Page 266	Page 268
<p>1 any -- but, again, keep in mind, 2 all the procedures I'm describing, 3 if I'm doing autologous fascial 4 sling, I'm using very long 5 polypropylene sutures. If I'm 6 doing a Burch suspension, I am 7 using 4 to 6 polypropylene 8 sutures. 9 It's the same. 10 BY MS. THOMPSON: 11 Q. So it's your opinion that 12 mesh devices like the TVT and sutures are 13 essentially the same? 14 A. No, that's not what I said. 15 I said the polypropylene material is 16 commonly used in urogynecologic surgery. 17 It is the same -- it is the same 18 material -- it's based upon the same base 19 material whether I'm doing an autologous 20 fascial sling, whether I'm doing a Burch 21 suspension, whether I'm doing an vaginal 22 apical suspension, whether I'm doing a 23 synthetic midurethral sling; 24 understanding that when I say synthetic</p>	<p>1 the intended procedure, it's the fascia 2 that is below it. 3 Q. And there's no suture when 4 you are doing a Burch procedure that's 5 placed underneath the urethra, is there? 6 A. Well, the Burch procedure, 7 as I commented earlier, has nothing to do 8 with the urethra. It's a procedure that 9 stabilizes the bladder neck. 10 Now, you know, I -- it just 11 occurred to me that, you know, we have 12 used the material of the sling in the 13 field of urogynecology for probably 14 between 30 and 50 years. You know, it's 15 surprising to me that if the latency for 16 sarcoma is 30 years, we should be seeing 17 those patients. In fact, we should be 18 seeing those patients now. 19 MS. THOMPSON: I don't think 20 there was a question about that, 21 so I'll move to strike that answer 22 as nonresponsive. 23 BY MS. THOMPSON: 24 Q. If Ethicon had information</p>
Page 267	Page 269
<p>1 midurethral sling I am specifically 2 referring to the Retropubic TVT device. 3 Q. Where is the suture placed 4 with an autologous sling? 5 A. Well, the -- there is an 6 autologous -- excuse me, there is a 7 polypropylene suture typically attached 8 at either end of the sling. It is 9 passed, in a similar manner, through a 10 vaginal incision, up through the space of 11 Retzius, up through the rectus fascia 12 into the subcutaneous space, analogous to 13 a TVT procedure. The difference is, it's 14 tied with tension across itself in that 15 manner. 16 Q. But there's no polypropylene 17 underneath the urethra when you do an 18 autologous sling procedure, is there? 19 A. Under the urethra? Well, 20 it's -- unless someone uses a smaller 21 piece of polypropylene to stabilize the 22 mesh under the urethra. And I have seen 23 that. 24 But I would say, you know,</p>	<p>1 that the fraying, roping and curling led 2 to a diminished tissue integration, is 3 that information you would want to know? 4 MR. SNELL: Form. 5 Foundation. 6 THE WITNESS: Again, I don't 7 rely upon Ethicon to communicate 8 that information. But I have had 9 discussions with them. I'm 10 aware -- they did communicate that 11 information to myself. 12 BY MS. THOMPSON: 13 Q. And is that information 14 other doctors should or would want to 15 know? 16 A. I can't speak to what other 17 doctors should or would want to know. 18 Q. If Ethicon had information 19 that the fraying, roping and curling of 20 mechanically cut mesh led to an increased 21 risk of infection, is that information 22 you would want to know from Ethicon? 23 MR. SNELL: Form and 24 foundation.</p>

68 (Pages 266 to 269)

Marc Toggia, M.D.

Page 270	Page 272
<p>1 THE WITNESS: Again, I would 2 want to know that information from 3 well-designed, high-level studies, 4 especially -- you know, that's 5 where I would seek that 6 information. 7 I'm sorry, if you're 8 satisfied with that answer, may I 9 take a break to go to the 10 bathroom? 11 MS. THOMPSON: Let me 12 just -- I have about, like, one 13 more question in this section. 14 THE WITNESS: May I be a 15 little more insistent that I be -- 16 MS. THOMPSON: Yeah, sure. 17 THE WITNESS: -- allowed to 18 take a break to go to the 19 bathroom? 20 MS. THOMPSON: Yes, sir. 21 VIDEO TECHNICIAN: We are 22 off the record. The time is 6:27 23 p.m. 24 - - -</p>	<p>1 needed a little bit more emphasis or 2 clarity. There was, maybe, a little bit 3 more specificity in some areas, a little 4 less specificity in other areas. 5 Q. Did the adverse reactions 6 section change at all during that time 7 period? 8 A. I'm not -- I can't give you 9 an independent recollection of that, as 10 we speak. To me, the instructions for 11 use, I focused on, you know, my -- my 12 focus is actually the instructions on 13 using the device. 14 Q. But this -- this document 15 would have been provided to physicians at 16 your training courses, correct? 17 A. I believe so, yes. 18 Q. In your report, I believe, 19 you stated that, IFU is clear, useful and 20 adequate to describe the procedure and 21 potential risks. 22 Does that sound right? 23 MR. SNELL: What page are 24 you on?</p>
Page 271	Page 273
<p>1 (Whereupon, a brief recess 2 was taken.) 3 - - - 4 VIDEO TECHNICIAN: We are 5 back on the record. The time is 6 6:40 p.m. 7 BY MS. THOMPSON: 8 Q. Dr. Toggia, had you reviewed 9 the instructions for use for the TVT when 10 you started using the device? 11 A. Yes, absolutely. 12 Q. And did you periodically 13 review the instructions for use as you 14 were teaching courses and acting as a 15 preceptor for Ethicon? 16 A. I did, yes. 17 Q. Do you know whether the 18 instructions for use changed over the 19 time period between 1998 and 2015? 20 A. Yes. My recollection is 21 that part of the work that I did with 22 them, particularly on the TVT EXACT® 23 product, we re-looked at the instructions 24 for use. Certain points were felt that</p>	<p>1 MS. THOMPSON: Page 17, at 2 the top of the page. 3 MR. SNELL: Thank you. 4 BY MS. THOMPSON: 5 Q. The IFU and professional 6 education for the TVT are clear, useful 7 and adequate to describe the procedure 8 and potential risks. 9 I'm just reading that from 10 your report. 11 A. I'm sorry, as usual, I'm a 12 little slower than -- than you all. 13 You're saying it's on Page 14 15? 15 Q. I think I said 17. 16 A. Yes. 17 Q. And then -- and you go on to 18 say that, Risks of SUI surgery are 19 obvious to surgeons and as surgeons, we 20 are expected to be aware of the risk in 21 light of our education, training and 22 experience. 23 A. Yes. 24 Q. Do you believe that a</p>

69 (Pages 270 to 273)

Marc Toggia, M.D.

Page 274	Page 276
<p>1 company --</p> <p>2 MR. SNELL: Let's go off the</p> <p>3 record.</p> <p>4 VIDEO TECHNICIAN: We're off</p> <p>5 the record at 6:43 p.m.</p> <p>6 - - -</p> <p>7 (Whereupon, a discussion off</p> <p>8 the record occurred.)</p> <p>9 - - -</p> <p>10 VIDEO TECHNICIAN: We are</p> <p>11 back on the record.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. Do you believe, Dr. Toggia,</p> <p>14 that a company can assume that doctors</p> <p>15 know certain risks and avoid warning of</p> <p>16 the risks as a result? That's a</p> <p>17 yes-or-no question.</p> <p>18 MR. SNELL: Form. He</p> <p>19 doesn't have to answer yes or no,</p> <p>20 he can answer how he sees fit.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Do you want me to repeat it?</p> <p>23 A. Well, I know that -- that</p> <p>24 this is one of -- you know, as a surgeon</p>	<p>1 to. That was my intention in making that</p> <p>2 statement.</p> <p>3 Q. So you're -- you're speaking</p> <p>4 of the general risk of surgery, not those</p> <p>5 that are specific to the TVT device?</p> <p>6 A. I'm talking about the risks</p> <p>7 that are specific to anti-incontinence</p> <p>8 procedures in women.</p> <p>9 MS. THOMPSON: We can stop</p> <p>10 there.</p> <p>11 THE WITNESS: No, keep</p> <p>12 going. That's fine. If you like.</p> <p>13 MR. SNELL: I'm hungry.</p> <p>14 MS. THOMPSON: We'll stop.</p> <p>15 VIDEO TECHNICIAN: We are</p> <p>16 off the record. The time is --</p> <p>17 THE WITNESS: That's fine.</p> <p>18 VIDEO TECHNICIAN: We are</p> <p>19 off the record at 6:47.</p> <p>20 - - -</p> <p>21 (Whereupon, a dinner recess</p> <p>22 was taken.)</p> <p>23 - - -</p> <p>24 VIDEO TECHNICIAN: We are</p>
Page 275	Page 277
<p>1 that does anti-incontinence procedure,</p> <p>2 I'm doing all the other procedures, this</p> <p>3 is an additional procedure that I'm</p> <p>4 doing, this procedure is based upon</p> <p>5 foundation principles that are somewhat</p> <p>6 common to the other procedures.</p> <p>7 And so, naturally, it</p> <p>8 follows that a risk of, say, bladder</p> <p>9 injury or a risk of bleeding, the risk of</p> <p>10 infections -- again, these are -- these</p> <p>11 are inherent risk and elemental risks of</p> <p>12 all surgical procedures.</p> <p>13 We're not teaching these</p> <p>14 procedures to non-surgeons to do. It's</p> <p>15 not that I'm picking a family practice</p> <p>16 doctor and saying, here, why don't you do</p> <p>17 this, you've got some patients.</p> <p>18 So it's -- I think it's</p> <p>19 predicated that, you know, a surgeon, you</p> <p>20 know, that was interested in using a TVT</p> <p>21 device in lieu of a different procedure</p> <p>22 that they were presently performing</p> <p>23 understands the general risks of surgery.</p> <p>24 I think that's what that statement speaks</p>	<p>1 back on the record. The time is</p> <p>2 7:24 p.m.</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Before we get started with</p> <p>5 the rest of the questions, Dr. Toggia,</p> <p>6 I've looked through the materials that</p> <p>7 you've brought.</p> <p>8 A. Yes.</p> <p>9 Q. And it looks to me like that</p> <p>10 top cardboard box has the materials that</p> <p>11 were not the ones related to your report</p> <p>12 and the materials that Mr. Snell provided</p> <p>13 you.</p> <p>14 MS. THOMPSON: So if we</p> <p>15 could just mark that box -- the</p> <p>16 contents of that box as an exhibit</p> <p>17 for the deposition.</p> <p>18 MR. SNELL: I don't know if</p> <p>19 that's accurate, but you can mark</p> <p>20 whatever you want to.</p> <p>21 MS. THOMPSON: That was what</p> <p>22 I kind of determined. Everything</p> <p>23 else looked like it was either</p> <p>24 depositions or documents or</p>

70 (Pages 274 to 277)

Marc Toglia, M.D.

Page 278	Page 280
<p>1 literature related to the report. 2 So we'll just do that. 3 MR. SNELL: Well, I did -- I 4 mean, we sent him the depositions 5 after his report and all the 6 exhibits and stuff. 7 MS. THOMPSON: Yeah, but I 8 don't need to mark those. 9 And then did you say that 10 you brought some thumb drives 11 also? I didn't see those. 12 THE WITNESS: It's 13 essentially this -- this material 14 here. 15 MS. THOMPSON: It's 16 basically this stuff, too? 17 THE WITNESS: I can 18 guarantee you it's no different. 19 MS. THOMPSON: Let's mark 20 these. 21 THE WITNESS: One of them is 22 simply -- one of them is simply 23 the expert reports. 24 MS. THOMPSON: So the box</p>	<p>1 you. 2 Do you believe that the 3 instructions for use are complete? 4 A. I believe that the 5 instructions for use do exactly that, 6 they -- they accurately describe the 7 instructions on how the product is to be 8 used. They provide the step-by-step 9 mechanics of the procedure. 10 Q. And complete and accurate in 11 terms of the listing of potential risks 12 as well? 13 A. I'm not sure what you mean 14 by "complete." I mean, I think it would 15 be impractical to reissue the instruction 16 for use every week or two. Those are 17 provided inside the box. 18 I don't -- I don't know what 19 form -- you know, what program is used to 20 determine how often to update those. 21 Q. Do you know if -- I believe 22 I already asked you the question about 23 how often they were updated. But I can't 24 remember the answer.</p>
Page 279	Page 281
<p>1 and the two thumb drives. 2 - - - 3 (Whereupon, Exhibit 4 Toglia-9, ETH.MESH 02026591-595, 5 Material Safety Data Sheet, was 6 marked for identification.) 7 - - - 8 (Whereupon, Exhibit 9 Toglia-10, Three Thumb drives 10 produced by Marc Toglia, M.D., was 11 marked for identification.) 12 - - - 13 BY MS. THOMPSON: 14 Q. Dr. Toglia, I think before 15 the break, we were just beginning to talk 16 about the instructions for use. 17 A. Yes. 18 Q. And I believe you said that 19 you reviewed them throughout the time 20 period and up to the present day that 21 you've been using TVT on a -- on some 22 kind of regular basis or -- 23 A. TVT and TVT EXACT®. 24 Q. TVT and TVT EXACT®, thank</p>	<p>1 A. No, you didn't ask me that 2 question. 3 To the best of my knowledge, 4 I'm aware of the initial and then the 5 update that occurred roughly around the 6 time the EXACT® was introduced, I 7 believe. 8 Q. And are you aware of an 9 update that occurred some time this year? 10 A. I am aware, yes, I did see 11 that. There was an update. 12 - - - 13 (Whereupon, Exhibit 14 Toglia-11, Selection of Materials 15 produced by Marc Toglia, M.D., was 16 marked for identification.) 17 - - - 18 BY MS. THOMPSON: 19 Q. I have marked the TVT 20 instructions for use as Exhibit Number 7. 21 And I just have a few questions for you. 22 A. This is the original? 23 Q. This, I believe, is from -- 24 from 2000.</p>

71 (Pages 278 to 281)

Marc Toglia, M.D.

Page 282	Page 284
<p>1 A. Please, do not ask me to 2 read anything from this. 3 Q. Oh, yeah, I'm sorry about 4 that. 5 A. Yeah, in Spanish. 6 Q. Let me read -- sorry this 7 the smallness of that print. 8 A. I think this is Turkish. 9 Q. We're not going to read the 10 Turkish. 11 MR. SNELL: I have 7 marked 12 as the Olmstead clinical thing. 13 And I think you just said this was 14 7. 15 MS. THOMPSON: You know 16 what, we had marked this earlier 17 as 7 and then -- 18 MS. COPE: What's the 19 sticker say on it? 20 MS. THOMPSON: The sticker 21 says -- Dr. Toglia, what does the 22 sticker say? 23 THE WITNESS: Mine says 7. 24 MS. THOMPSON: Yeah, we put</p>	<p>1 close. And we will not be reading the 2 Turkish or Spanish or any other language. 3 On the -- 4 A. There's Italian. 5 Q. And Italian. Do you know 6 Italian? 7 A. No. 8 Q. On the second page, Bates 9 number 380, under TVT device, it states, 10 This bidirectional elastic property 11 allows adaptation to various stresses 12 encountered in the body. 13 A. Where do you see that? 14 Q. Under TVT device, the second 15 paragraph, the last sentence. 16 A. And, I'm sorry, this is from 17 when? 18 Q. 2000. 19 A. Okay. I'll accept that. 20 Q. The bidirectional elastic 21 property allows adaptation to various 22 stresses encountered in the body. 23 Do you know what the basis 24 for that statement is?</p>
Page 283	Page 285
<p>1 a 7 instead, so let's change it to 2 8. 3 - - - 4 (Whereupon, a discussion off 5 the record occurred.) 6 - - - 7 MS. THOMPSON: Off the 8 record till we get our exhibit 9 straight. 10 VIDEO TECHNICIAN: We are 11 off the record. It's 7:30 p.m. 12 - - - 13 (Whereupon, a discussion off 14 the record occurred.) 15 - - - 16 VIDEO TECHNICIAN: We are 17 back on the record. 18 BY MS. THOMPSON: 19 Q. Dr. Toglia, these were how 20 the instructions for use were produced to 21 us, and I apologize for the small print. 22 But I'll read you what I 23 want to ask you about, and if you -- if 24 you can tell at least that it's kind of</p>	<p>1 MR. SNELL: Objection. 2 Completeness. 3 Go ahead. 4 THE WITNESS: I don't know 5 the direct -- what the direct 6 basis is. 7 BY MS. THOMPSON: 8 Q. Would you agree that the 9 bidirectional elastic property allows 10 adaptation to various stresses 11 encountered in the body with the TVT 12 device? 13 A. I would assume that it 14 allows adaptations within two directions, 15 bidirectional. 16 Q. And is it your understanding 17 that that's what the TVT does, how the 18 TVT behaves? 19 MR. SNELL: Form. 20 THE WITNESS: Again, I'm not 21 familiar with the context, so I 22 don't -- can't answer that 23 question, sorry. 24 BY MS. THOMPSON:</p>

72 (Pages 282 to 285)

Marc Toggia, M.D.

Page 286	Page 288
<p>1 Q. Did you ever ask Ethicon, 2 during the time that you were serving as 3 a preceptor, what was meant by that 4 statement? 5 A. I don't believe I ever asked 6 them what was meant by that statement. 7 Q. On the next page, under 8 instructions for use, the first sentence, 9 The procedure can be carried out under 10 local anesthesia, but it can also be 11 performed using regional or general 12 anesthesia. 13 Do you perform most of your 14 TVTs under local or general? 15 A. The majority of our 16 procedures, the vast majority, are 17 performed with -- not with general 18 anesthesia. It's local anesthesia with 19 monitored anesthesia care, which is 20 intravenous sedation. 21 There are times, of course, 22 the patient may request general 23 anesthesia. There are times that the 24 anesthesiologist might be insistent on</p>	<p>1 would talk about whether -- how do 2 you -- how do you set the mesh in 3 its final position, whether you 4 use a, quote/unquote, cough test, 5 which, obviously, you couldn't do 6 with general anesthesia, do you 7 simply eyeball it, use a spacer. 8 I think, really, the 9 underlying message was always that 10 you don't tension -- you don't put 11 tension on the mesh or position 12 the mesh in an obstructive manner. 13 I don't believe, nor am I 14 aware, that the success rates are 15 higher. I don't believe that 16 there are any high-quality studies 17 that randomize people to one or 18 the other. 19 BY MS. THOMPSON: 20 Q. Is that information that 21 other physicians would like to have, do 22 you believe? 23 A. I know that in the course of 24 training, when I would train a physician,</p>
Page 287	Page 289
<p>1 general anesthesia. 2 I present it as a procedure 3 that we advocate for local with monitored 4 anesthesia care. 5 Q. And with the MAC anesthesia, 6 the patient is asleep, although not under 7 a full general anesthesia, correct? 8 A. As you know, sleep is not a 9 medical term. I would say the patient is 10 not conscious. 11 Q. If Ethicon had information 12 that the success rate was higher if a 13 local anesthesia was used, is that 14 information that you, as a physician, 15 would like to have? 16 MR. SNELL: Form. 17 Foundation. 18 THE WITNESS: I've got to be 19 honest with you, I would not allow 20 Ethicon to -- I mean, I'm the 21 surgeon, I do the procedures, they 22 don't. I don't think the form of 23 anesthesia has any influence. 24 I think that early on we</p>	<p>1 it's something that we would discuss, you 2 know, as -- as an option. 3 Q. Under adverse reactions, 4 Bates Number 3883 -- 5 A. Yes. 6 Q. -- the IFU states, 7 Transitory local irritation at the wound 8 site and a transitory foreign body 9 response may occur. This response could 10 result in extrusion, erosion, fistula 11 formation and inflammation. 12 Is that a correct statement? 13 A. I would assume if it was 14 included in here, that they believe that 15 that was a correct statement. 16 I can't tell you that I 17 personally have ever witnessed any of 18 that. 19 Q. And that's because, of your 20 3,000 patients with pelvic mesh, you've 21 never observed a foreign body response, 22 correct? 23 MR. SNELL: Objection. 24 Misstates.</p>

73 (Pages 286 to 289)

Marc Toggia, M.D.

Page 290	Page 292
<p>1 THE WITNESS: I'm speaking, 2 in this case, specific to the -- 3 to the TVT procedure. 4 Again, it's at the wound 5 site, so result of the suture 6 material, cautery, how rough you 7 are with the tissue. 8 I don't -- I don't interpret 9 this as having anything to do with 10 the mesh, per se. I read it 11 literally, which is that there may 12 be local irritation at the wound 13 site and that it is a transient 14 phenomenon. 15 BY MS. THOMPSON: 16 Q. Under actions, the IFU 17 states, Animal studies show that 18 implantation of PROLENE® mesh elicits a 19 minimal inflammatory reaction in tissues, 20 which is transient and is followed by the 21 deposition of a thin fibrous layer of 22 tissue which can grow through the 23 interstices of the mesh, thus 24 incorporating the mesh into adjacent</p>	<p>1 Do you remember when you 2 first became a paid consultant for 3 Ethicon? 4 A. As I stated earlier, I do 5 recall, prior to the launch of the 6 product, being part of a focus group in 7 which I was asked to give an opinion on 8 the feasibility of this as a new 9 procedure, and I was paid for that. 10 Q. And we're talking about the 11 TVT in 1998 or 1999, roughly? 12 A. To be honest with you, if I 13 had to give you a guess, this was '96, 14 '97. I'm pretty sure it was '96. 15 Q. And do you recall when you 16 became a proctor for Ethicon? 17 A. I'm going to say 2002, 18 perhaps. 19 Q. And did you have a contract 20 for either of those positions, that 21 you're aware of? 22 A. Well, the focus group, of 23 course, was a single event. The -- at 24 some point in time, there would be a --</p>
Page 291	Page 293
<p>1 tissue. The material is not absorbed nor 2 is it subject to degradation or the 3 weakening by the action of tissue 4 enzymes. 5 A. I believe that's an accurate 6 statement, yes. 7 Q. I believe that's all the 8 questions I have on the IFU. 9 MS. THOMPSON: Off the 10 record for a couple minutes, 11 please. 12 VIDEO TECHNICIAN: We are 13 off the record. The time is 7:39 14 p.m. 15 - - - 16 (Whereupon, a discussion off 17 the record occurred.) 18 - - - 19 VIDEO TECHNICIAN: We are 20 back on the record. 21 BY MS. THOMPSON: 22 Q. Dr. Toggia, I'm going to ask 23 you some questions about your work with 24 Ethicon.</p>	<p>1 there was probably a contract regarding 2 proctoring. And I recall every year 3 that -- that would be a new and usually 4 different terms. 5 Q. Do you recall how you were 6 compensated for being a proctor for 7 Ethicon? 8 A. Yes. 9 Q. How much were you paid? 10 A. It depended upon the 11 situation, if I was doing a procedure 12 within my institution, did I have to 13 drive 60 miles, did I get on an airplane. 14 So it would vary. 15 I would -- I would 16 guesstimate maybe \$1,500 at the lower 17 end, \$2,500, maybe \$3,000. You know, 18 sometimes there would be one person, it 19 might be up to three people. There was 20 probably a factor for that. 21 Q. So that was per preceptee or 22 group of preceptees that you were paid 23 between \$1,500 and \$5,000? 24 A. No \$5,000; \$2,500, \$3,000.</p>

74 (Pages 290 to 293)

Marc Toggia, M.D.

Page 294	Page 296
<p>1 Q. \$2,500, I mean.</p> <p>2 A. Again, I think the higher</p> <p>3 end would speak to more than one. The</p> <p>4 lower end would speak to location and</p> <p>5 maybe one. There wasn't that significant</p> <p>6 of a difference, I don't recall. I mean,</p> <p>7 the highest might have been \$3,000.</p> <p>8 They would classify you.</p> <p>9 Maybe, in the beginning they would call</p> <p>10 me a local proctor. At some point, I was</p> <p>11 a national proctor. Physicians might fly</p> <p>12 in from other locations. I would -- I'm</p> <p>13 assuming that the reimbursement may have</p> <p>14 been a little higher. I never did a</p> <p>15 large volume --</p> <p>16 Q. Do you know --</p> <p>17 A. -- proctoring.</p> <p>18 Q. -- offhand how many doctors</p> <p>19 that you proctored over the years with</p> <p>20 Ethicon?</p> <p>21 A. I don't know offhand the</p> <p>22 number of doctors I proctored. If I were</p> <p>23 to throw out a term, like, fifteen,</p> <p>24 twenty over a -- over a ten-year period</p>	<p>1 would be between \$12,000 and \$30,000 that</p> <p>2 you were paid by Ethicon?</p> <p>3 A. I would say it's probably</p> <p>4 between \$6,000 and \$20,000. I don't know</p> <p>5 for sure. It was not, in my estimation,</p> <p>6 substantial.</p> <p>7 - - -</p> <p>8 (Whereupon, Exhibit</p> <p>9 Toggia-12, ETH.MESH 11843352-364,</p> <p>10 Consulting Agreement Requisition</p> <p>11 Form, was marked for</p> <p>12 identification.)</p> <p>13 - - -</p> <p>14 MS. THOMPSON: We have this</p> <p>15 marked as an exhibit. I only have</p> <p>16 one copy of the contract. I'm not</p> <p>17 going to ask any more questions</p> <p>18 about it, but if you want to look</p> <p>19 at that, that's fine.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. Do you have records of the</p> <p>22 money that you received from Ethicon for</p> <p>23 payment for your services?</p> <p>24 A. As in payment stubs or -- I</p>
Page 295	Page 297
<p>1 of time.</p> <p>2 And the -- in the context of</p> <p>3 proctor, I'm talking about a physician</p> <p>4 that was in the operating room with a</p> <p>5 patient, not necessarily a lab -- you</p> <p>6 know, a lab situation, a dry lab</p> <p>7 situation or anything like that.</p> <p>8 Q. We have a contract from 2006</p> <p>9 that says you would be paid a maximum of</p> <p>10 \$100,000 for the year.</p> <p>11 Do you recall how much you</p> <p>12 were actually paid --</p> <p>13 A. In 2006?</p> <p>14 Q. -- in 2006?</p> <p>15 A. In general, it would</p> <p>16 probably be something like \$12,000, maybe</p> <p>17 \$15,000.</p> <p>18 I would say -- I think the</p> <p>19 highest I had gotten -- and, again, I</p> <p>20 mean, a total number and this goes</p> <p>21 beyond -- was maybe \$30,000. But I have</p> <p>22 to tell you, that probably includes more</p> <p>23 of the design work that I may have done.</p> <p>24 Q. So in 2006, your estimation</p>	<p>1 haven't done anything with them recently.</p> <p>2 I mean -- I mean, there may have been one</p> <p>3 case in 2013. There may have been none</p> <p>4 for the preceding several years.</p> <p>5 So, certainly, as we go back</p> <p>6 five or six years, I don't think I would</p> <p>7 have -- you know, I would have the</p> <p>8 original invoices or records, no.</p> <p>9 Q. When was the last time you</p> <p>10 proctored a physician for Ethicon?</p> <p>11 A. To the best of my knowledge,</p> <p>12 there was one physician that I proctored</p> <p>13 who was within my system, and I want to</p> <p>14 say that was maybe 2013. I couldn't -- I</p> <p>15 mean, to my mind, it seems like it was</p> <p>16 longer ago than that.</p> <p>17 Q. Between 2006 and 2013, did</p> <p>18 you believe that you had a contract each</p> <p>19 year with Ethicon for various services?</p> <p>20 A. I believe so. Again, my</p> <p>21 role with Ethicon changed with time as I</p> <p>22 looked at different projects or worked on</p> <p>23 different projects.</p> <p>24 Q. We have an Excel spreadsheet</p>

75 (Pages 294 to 297)

Marc Toggia, M.D.

Page 298	Page 300
<p>1 that shows \$30,000 in 2011, \$6,000 in 2 2010 and \$15,000 in 2013. 3 Does that sound about right? 4 MR. SNELL: Object to the 5 form. Foundation. 6 THE WITNESS: I believe that 7 that's in the range of the numbers 8 that I had -- that I had 9 recollected. 10 MS. THOMPSON: And we marked 11 that spreadsheet as Exhibit 13, if 12 you want to look at that. 13 THE WITNESS: Sure. 14 - - - 15 (Whereupon, Exhibit 16 Toggia-13, Spreadsheet, was marked 17 for identification.) 18 - - - 19 MR. SNELL: This doesn't 20 have a Bates number on it. Where 21 is it from? 22 MS. COPE: I can get you the 23 number when we print them out. 24 They're not produced, in Excel</p>	<p>1 gifts from Ethicon or employees of 2 Ethicon? 3 A. Not that I'm aware of, no. 4 Q. Did Ethicon reimburse your 5 travel expenses and travel time while you 6 were working as a consultant for them? 7 A. Yes. 8 Q. And were there times that 9 you also gave presentations at dinner 10 meetings for doctors for Ethicon? 11 A. There might have been. I 12 don't recall that being a common 13 scenario. But I would -- I would 14 venture, yes, there probably were 15 meetings that a presentation -- and, 16 again, I would have trouble separating 17 the TVT stuff from something else. 18 Q. And I believe we have an 19 invoice in 2009 for a \$3,000 speaking 20 stipend for dinner meeting and in 2008, 21 \$3,095.95 for a dinner speaking meeting. 22 Does that sound like that 23 probably happened? 24 A. I'm a pretty cheap date, so</p>
Page 299	Page 301
<p>1 format, with a Bates number. 2 MR. SNELL: But it has a 3 Bates number, a document number 4 attached to any native file if 5 it's a produced document -- 6 MS. COPE: And what I'm 7 saying is I can get that -- 8 MR. SNELL: Oh, you can get 9 that? 10 MS. COPE: -- to you. But 11 when we print it out -- 12 MR. SNELL: I got you. 13 THE WITNESS: I'll be honest 14 with you, I can't read any of 15 this. But I'm happy to accept the 16 figures you threw out. But please 17 don't ask me to read the details. 18 I can read my -- I can read 19 my name, I see that, I recognize 20 that. 21 BY MS. THOMPSON: 22 Q. So we don't have time to 23 have you try to read that, correct? 24 Did you ever receive any</p>	<p>1 it kind of sounds like something that we 2 might have done. 3 Q. \$3,000 for a dinner 4 presentation doesn't sound that cheap to 5 me. 6 A. No? 7 Q. Does it to you? 8 A. Time away from one's family 9 after one has already worked a ten- or 10 twelve-hour day? I'd say that's pretty 11 cheap, but that's just my personal 12 opinion. 13 Q. And at those presentations, 14 you would typically show a PowerPoint? 15 A. We may have shown a 16 PowerPoint. It could have been more of 17 an informal discussion. I mean, 18 PowerPoints are usually one of my 19 preferred methods to lead a discussion. 20 Q. But you don't remember 21 specifically at the dinner meetings that 22 you did for Ethicon whether there was a 23 PowerPoint involved? 24 A. I mean, recognizing that</p>

76 (Pages 298 to 301)

Marc Toggia, M.D.

Page 302	Page 304
<p>1 we're in a public restaurant somewhere in 2 Philadelphia, I could see it going either 3 way, based upon the venue. 4 Q. Do you remember preparing 5 slide presentations for any talks at 6 Ethicon? 7 A. I'm sure that I have 8 prepared talks. I don't -- I don't 9 recall. 10 Q. And Ethicon would pay for 11 your travel and meals for those meetings 12 as well? 13 A. They would pay for travel. 14 I'll be very honest with you, I don't 15 usually bill for meals. I have to eat 16 anyhow, that's not usually something I 17 would bill myself. 18 Q. I think we already talked 19 about the clinical study agreements that 20 you had with Ethicon for the TVT. 21 Was there also an agreement 22 for -- 23 A. So, I'm sorry, I didn't -- I 24 don't recall I had a study agreement with</p>	<p>1 and I was simply reviewing those results. 2 But I did not participate in 3 a PROSIMATM study. 4 Q. Do you remember whether you 5 were paid for whatever service you 6 provided for the PROSIMATM registry? 7 MR. SNELL: Form. 8 THE WITNESS: I'll be very 9 honest with you, I don't recall 10 really having any involvement with 11 PROSIMATM. 12 BY MS. THOMPSON: 13 Q. Why not? 14 A. I don't know. I don't know 15 whether -- whether I was -- it was 16 something that didn't meet my clinical 17 interest, whether they decided that they 18 were not in need of my services. 19 I remember PROSIMATM as a 20 concept. I know there was a clinical 21 trial done. This was not a project that 22 I was active on. 23 Q. And I can't remember from 24 earlier, did you use the PROSIMATM at</p>
Page 303	Page 305
<p>1 Ethicon. 2 What are you referring to? 3 - - - 4 (Whereupon, Exhibit 5 Toggia-14, ETH.MESH 03617772, 6 Consultant Invoice Dated 5/28/09, 7 was marked for identification.) 8 - - - 9 MR. SNELL: What number is 10 this? 11 THE WITNESS: 15. 12 BY MS. THOMPSON: 13 Q. Do you remember an agreement 14 to provide services relating to the 15 PROSIMATM registry? 16 A. This was not a study 17 agreement. I think I -- I just simply 18 read material. 19 PROSIMATM was not a 20 procedure I ever performed or performed 21 clinically. I -- it's a secrecy 22 agreement, which means, I think, they 23 basically talk to me about the procedure. 24 Maybe they had results from a registry</p>	<p>1 all? 2 A. No. That's what I'm 3 speaking to. 4 Q. In the TVT versus TVT-S 5 study that you participated in -- 6 A. Yes. 7 Q. -- were you paid by 8 Ethicon -- 9 A. No. 10 Q. -- for your participation in 11 that study? 12 A. No. 13 Q. I believe the disclosure on 14 that article was that you were 15 preceptor -- preceptor for Ethicon at the 16 time the paper was published? 17 A. Yes, that would be a 18 separate. 19 Q. Was that the full extent of 20 your employment with Ethicon? 21 MR. SNELL: Objection. 22 Form. He wasn't employed by 23 Ethicon. 24 MS. THOMPSON: Sorry, my</p>

77 (Pages 302 to 305)

Marc Toggia, M.D.

Page 306	Page 308
<p>1 fault.</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. Your financial arrangement</p> <p>4 with Ethicon?</p> <p>5 A. I'm sure you understand that</p> <p>6 the publication occurred years after the</p> <p>7 actual study was completed. I would</p> <p>8 think that the disclosure came at the</p> <p>9 time of submission of the manuscript for</p> <p>10 publication. So it wasn't during the</p> <p>11 study.</p> <p>12 I mean, I think that my</p> <p>13 relationship with Ethicon was fairly</p> <p>14 consistent over those -- over that</p> <p>15 ten-year period of time.</p> <p>16 So I have no reason to -- I</p> <p>17 hope you understand the differential I'm</p> <p>18 trying to make, because I'm trying to be</p> <p>19 accurate.</p> <p>20 I assume that I was -- I was</p> <p>21 a preceptor at the same time -- I mean, I</p> <p>22 trained some of the -- I trained some of</p> <p>23 the other investigators in the trial.</p> <p>24 I'm -- I pretty strongly don't think</p>	<p>1 A. You have not asked me that.</p> <p>2 Q. I didn't think so.</p> <p>3 Could I ask you that</p> <p>4 question, how many PROLIFT® devices did</p> <p>5 you actually place?</p> <p>6 A. You know, according to the</p> <p>7 information that I just sort of tracked</p> <p>8 upstairs here, it was probably in the</p> <p>9 vicinity of about 400.</p> <p>10 Q. And when did you stop using</p> <p>11 PROLIFT®?</p> <p>12 A. Once it was removed from the</p> <p>13 market.</p> <p>14 Q. Are you aware that your</p> <p>15 website still includes PROLIFT® as an</p> <p>16 option for women who have prolapse?</p> <p>17 A. I am aware. And if I had</p> <p>18 the time or the knowledge to remove it, I</p> <p>19 certainly would. But thank you for</p> <p>20 reminding me of that outdated</p> <p>21 information.</p> <p>22 Q. You're welcome.</p> <p>23 Did Ethicon also help you</p> <p>24 advertise your practice?</p>
Page 307	Page 309
<p>1 there was -- I charged -- Ethicon did not</p> <p>2 pay me for any of that nor did they</p> <p>3 reimburse me for travel. That's just</p> <p>4 something that I did because these were</p> <p>5 my colleagues, if that makes sense to</p> <p>6 you.</p> <p>7 Q. Sure. And how many times</p> <p>8 did you do cadaver labs for Ethicon,</p> <p>9 ballpark?</p> <p>10 A. It could be four. It could</p> <p>11 be eight. I would say maybe closer to</p> <p>12 the four.</p> <p>13 Q. For what products did you do</p> <p>14 cadaver labs?</p> <p>15 A. You know, oftentimes,</p> <p>16 because cadaver labs are so expensive to</p> <p>17 obtain the materials, it certainly was</p> <p>18 typical that on one day we might have</p> <p>19 been working with TVT-Secur, we might</p> <p>20 have been working with PROLIFT®, we might</p> <p>21 have been -- I'm sure that we worked with</p> <p>22 Retropubic and Obturator.</p> <p>23 Q. Did I ask you how many</p> <p>24 PROLIFT® devices you actually placed?</p>	<p>1 A. There was a brief window of</p> <p>2 time that Ethicon, in professional</p> <p>3 education, was interested in helping to</p> <p>4 raise awareness of pelvic floor</p> <p>5 dysfunction and the treatments for that.</p> <p>6 My -- I only -- I only</p> <p>7 remember one situation in which we placed</p> <p>8 an ad in a magazine. I think it</p> <p>9 corresponded to when I had hired a new</p> <p>10 partner, and I just was interested in</p> <p>11 letting people know that our practice had</p> <p>12 these two physicians.</p> <p>13 I don't think that that ran</p> <p>14 for more than three months. That's my</p> <p>15 only recollection. It was kind of a, you</p> <p>16 know, what do you think of this idea, you</p> <p>17 know. I think we just -- we did it on a</p> <p>18 one-time basis.</p> <p>19 Q. But in addition to the money</p> <p>20 that you were paid by Ethicon for various</p> <p>21 preceptor trips, dinner presentations, et</p> <p>22 cetera, they did provide advertisement</p> <p>23 for your practice?</p> <p>24 MR. SNELL: Objection to</p>

78 (Pages 306 to 309)

Marc Toggia, M.D.

Page 310	Page 312
<p>1 form.</p> <p>2 THE WITNESS: In a sense. I</p> <p>3 mean, it's not that they paid me</p> <p>4 and I paid for the ad. Like, with</p> <p>5 the clinical trials, I didn't get</p> <p>6 the money, the money was -- would</p> <p>7 have been -- would go through our</p> <p>8 channels, that's what the Lankenau</p> <p>9 Institute of Medical Research</p> <p>10 does; I believe that they may have</p> <p>11 been involved with the clinical.</p> <p>12 So the money went somewhere.</p> <p>13 It's not -- not money that I</p> <p>14 touched, so to speak.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Going back to something you</p> <p>17 mentioned a minute ago.</p> <p>18 What information did you</p> <p>19 just check upstairs?</p> <p>20 A. I checked in with my wife</p> <p>21 upstairs, and I looked over my report.</p> <p>22 Q. You mentioned that you,</p> <p>23 after checking the information upstairs,</p> <p>24 you thought that you had done about 400</p>	<p>1 have, in frustration, made comments.</p> <p>2 I've got to be honest with you, I don't</p> <p>3 think it helped or hurt in a significant</p> <p>4 sense.</p> <p>5 But, occasionally, I</p> <p>6 might -- might have gotten my feelings,</p> <p>7 you know, hurt.</p> <p>8 Q. Do you remember sending an</p> <p>9 e-mail to someone at Ethicon about lost</p> <p>10 business as a result of some of the sales</p> <p>11 reps activities, Eileen's specifically?</p> <p>12 A. I don't. I'm aware of an</p> <p>13 e-mail, I don't -- can't tell you that I</p> <p>14 remember, at the time, again, sort of the</p> <p>15 context.</p> <p>16 But, yeah, there was --</p> <p>17 there was a point that I was a little</p> <p>18 grumpy about things. Although I may have</p> <p>19 been simply misdirecting my frustration</p> <p>20 in the wrong direction, more than likely.</p> <p>21 Q. And was that because they</p> <p>22 had trained one of your referral</p> <p>23 physicians who then became a competing</p> <p>24 physician?</p>
Page 311	Page 313
<p>1 PROLIFT® procedures, that's what I was</p> <p>2 asking about.</p> <p>3 A. Oh, excuse me --</p> <p>4 MR. SNELL: That's in his</p> <p>5 head.</p> <p>6 THE WITNESS: It's just --</p> <p>7 MS. THOMPSON: Oh, I took</p> <p>8 it --</p> <p>9 THE WITNESS: No, no. I'm</p> <p>10 so sorry.</p> <p>11 MS. THOMPSON: Oh, I took it</p> <p>12 literally.</p> <p>13 THE WITNESS: No, no.</p> <p>14 MS. THOMPSON: I'm glad we</p> <p>15 clarified that.</p> <p>16 MR. SNELL: That was taken</p> <p>17 out of context.</p> <p>18 THE WITNESS: My apologies.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Dr. Toggia, did you ever</p> <p>21 complain to Ethicon that its business</p> <p>22 practices affected the income received by</p> <p>23 your practice?</p> <p>24 A. Oh, I'm sure that I may</p>	<p>1 A. I mean, this is referring to</p> <p>2 Dr. Finnegan. Dr. Finnegan is a</p> <p>3 colleague of mine.</p> <p>4 I don't -- I see the</p> <p>5 statement. I understand what that seems</p> <p>6 to be. I can't tell you that I ever felt</p> <p>7 like that that hurt my business. I</p> <p>8 think, really, what I -- the message that</p> <p>9 I was trying to do here -- the message I</p> <p>10 was trying to get across here, which I</p> <p>11 will tell you, at this point, I was</p> <p>12 completely ineffective, I was simply</p> <p>13 trying to say, look, if we're going to</p> <p>14 train physicians, you know, within my</p> <p>15 department, I would like to be the</p> <p>16 trainer, in that I would like to have a</p> <p>17 relationship with people, so if they're</p> <p>18 doing these procedures and they want</p> <p>19 advice, I would like to be viewed as --</p> <p>20 as someone they could speak to.</p> <p>21 And I think that's really</p> <p>22 what I was trying to get at, although, I</p> <p>23 admit, I did not state it -- I did not</p> <p>24 state it well.</p>

79 (Pages 310 to 313)

Marc Toggia, M.D.

Page 314	Page 316
<p>1 And, to be honest with you, 2 I was being a bit dramatic here. I have 3 a very cordial relationship with 4 Finnegan. I don't think he's had any 5 effect on my business whatsoever. 6 - - - 7 (Whereupon, Exhibit 8 Toggia-15, ETH.MESH 10399348, 9 4/29/09 E-mail from Patricia Beach 10 to Judi Gauld; Subject: FW: 11 PROSIMATM Registry, was marked for 12 identification.) 13 - - - 14 BY MS. THOMPSON: 15 Q. Did Ethicon pay for 16 community education or other events that 17 may have resulted in increased patients 18 or business for you? 19 A. It was not uncommon -- when 20 you say "paid for," let me, please, just 21 sort of qualify that. 22 So we would -- from time to 23 time, we would give community education 24 events on the hospital campus. The</p>	<p>1 like -- in that regard, no. 2 Q. Do any of the committees or 3 organizations or employers have policies 4 regarding conflict of interest or 5 accepting money from industry sources? 6 A. You're talking -- 7 MR. SNELL: Form. 8 THE WITNESS: You're talking 9 about my employment? 10 BY MS. THOMPSON: 11 Q. Yes. 12 A. So my employment contracts 13 do have language that allows me to 14 function as a consultant to industry, to 15 publish articles, books, where I might 16 get a royalty. 17 Q. And the academic 18 institutions with which you're affiliated 19 don't have policies regarding accepting 20 payments from industry? 21 A. Not as they affect me, since 22 I'm not -- you know, that's usually the 23 case if that's the person who is paying 24 your salary.</p>
Page 315	Page 317
<p>1 company would provide snacks and 2 refreshments. I don't think that there 3 was ever a situation where I was paid to 4 give that presentation. The 5 presentations, typically, were general 6 presentations; I'm going to talk to you 7 about incontinence, whether that be urge 8 incontinent, whether that be stress 9 incontinence; I'm going to talk to you 10 about prolapse. 11 Does that make sense? But I 12 don't think I was ever paid -- I was 13 never financially rewarded for that. 14 They simply provided snacks and 15 refreshments in that regard. 16 Q. Are there -- are any of the 17 awards or recognitions that you received 18 the result of nominations from Ethicon? 19 A. No, not that I'm -- no. I 20 was never a high priority for them, to be 21 honest with you, given that, you know, we 22 had very well known -- other consultants, 23 I'm sure you must be aware, within a 24 short distance from here. I was kind of</p>	<p>1 I think it really -- those 2 kind of relationships say, look, you 3 can't sort of double dip. You can't 4 be -- you can't be getting paid as a 5 physician and, simultaneously, at that 6 same time. 7 Q. Have you disclosed your 8 financial relationship with Ethicon to 9 committees that you've served on, for 10 example, AUGS? 11 A. Of course. We're very 12 transparent. I mean, the public is 13 aware. I mean, you've got The Sunshine 14 Act. There are -- there -- certainly 15 it's public knowledge. 16 It's also public knowledge 17 what, you know, CMS has paid me, which is 18 Medicare. 19 Q. And you've disclosed your 20 conflict of interest with Ethicon on all 21 your publications since the time that you 22 began working for Ethicon? 23 MR. SNELL: Form. 24 THE WITNESS: I don't work</p>

80 (Pages 314 to 317)

Marc Toggia, M.D.

Page 318	Page 320
<p>1 for -- I never worked for Ethicon. 2 I don't -- 3 BY MS. THOMPSON: 4 Q. Doing work for Ethicon? 5 MR. SNELL: Same objection. 6 THE WITNESS: I have done -- 7 I have done contractual work with 8 Ethicon. I don't know what I -- I 9 don't have any responsibility to 10 report to them what I publish or 11 what else that I do. 12 BY MS. THOMPSON: 13 Q. Do you disclose the work 14 that you do with Ethicon to residents 15 that you're teaching? 16 A. Yes. 17 Q. Has Ethicon ever asked you 18 to attend society meetings and give 19 presentations or be represented at 20 exhibitions at the society meeting? 21 A. I don't believe I've ever 22 done anything like that for Ethicon. 23 Q. Dr. Toggia, did you have a 24 sexual relationship with Kathleen Feeney?</p>	<p>1 Toggia-16, ETH.MESH 11838868-869, 2 5/30/07 E-mail from Kathleen 3 Feeney to Cindy Pypcznski; 4 Subject: FW: Surgery at Lankenau, 5 was marked for identification.) 6 - - - 7 BY MS. THOMPSON: 8 Q. Did you -- did you -- do you 9 recall an e-mail when she was leaving the 10 company in which she provided you with 11 her personal e-mail address? 12 A. I know that Kathleen Feeney 13 was interested in me, perhaps, writing a 14 letter of recommendation. I know that 15 she had asked me could she have -- could 16 I be a reference, and in that context 17 there may have been. 18 Q. Do you remember asking her 19 what she would use as her name when she 20 left Ethicon. And she said -- replied 21 Kath Toggia? 22 A. I -- Kathleen would make 23 offhanded comments from time to time. I 24 can't say I can't remember her ever</p>
Page 319	Page 321
<p>1 A. No. 2 MR. SNELL: Objection. 3 BY MS. THOMPSON: 4 Q. Did you have an affair with 5 Kathleen Feeney? 6 MR. SNELL: Same objection. 7 THE WITNESS: I don't know 8 what you're referring to. 9 BY MS. THOMPSON: 10 Q. Did you have anything other 11 than a professional relationship with 12 her? 13 MR. SNELL: Same objection. 14 Argumentative. 15 THE WITNESS: You know, I 16 mean -- you know, we were friends, 17 in a sense, although it's not a 18 friendship that extended beyond, 19 like, when she left the company. 20 It quickly, you know -- I don't 21 know where you're coming from. 22 This -- Kathleen Feeney is -- 23 - - - 24 (Whereupon, Exhibit</p>	<p>1 saying that. But I wouldn't be 2 surprised. She was teasing me at the 3 time, of course. 4 MS. THOMPSON: I think 5 that's all the questions I have 6 for you. Thank you, Dr. Toggia, 7 for your time. 8 MS. COPE: Sorry, just 9 wanted to clarify. That one 10 document that didn't have the 11 Bates number, I got the Bates 12 number, if you want to stick that 13 on the exhibit. 14 MR. SNELL: Let's go off the 15 record. 16 VIDEO TECHNICIAN: We are 17 off the record. The time is 8:10 18 p.m. 19 - - - 20 (Whereupon, a brief recess 21 was taken.) 22 - - - 23 VIDEO TECHNICIAN: This 24 marks the beginning of Video</p>

81 (Pages 318 to 321)

Marc Toggia, M.D.

Page 322	Page 324
<p>1 Number 5. We are back on the 2 record. The time is 8:17 p.m. 3 - - - 4 EXAMINATION 5 - - - 6 BY MR. SNELL: 7 Q. Dr. Toggia, we're back. I 8 just have a few follow-up questions, 9 following up on plaintiffs' counsel's 10 questions to you. 11 First of all, I believe you 12 were trying to explain your methodology 13 to plaintiffs' counsel. 14 Can you state your 15 methodology that you utilized in 16 assessing the utility and the safety of 17 the TVT device for its intended use to 18 treat stress urinary incontinence? 19 A. Yes. So the question that 20 was put before me is whether or not the 21 TVT was well suited for its intended 22 purpose, which was the treatment of 23 stress urinary incontinence in women, 24 whether or not that -- it achieved that</p>	<p>1 internal Ethicon communications. I 2 looked at some of the -- the expert 3 opinions provided by the plaintiffs' 4 side. We looked at, you know, animal 5 studies, in vitro studies. Although, 6 again, recognizing that those are really 7 Level 5 evidence data, that you really 8 can't draw any clinical inference or -- 9 or application directly to the TVT 10 device. Those were looked at as well. 11 Q. You saw that plaintiffs' 12 experts cited to a bunch of hernia 13 documents, prolapse documents, animal 14 studies in their reports? 15 A. Yes, I saw that. Yes. 16 Q. And I believe you earlier 17 told plaintiffs' counsel you were shocked 18 at their methodology; is that accurate? 19 A. I would -- I would -- 20 MS. THOMPSON: Object to 21 form. 22 THE WITNESS: I was -- I did 23 not find their methodology to be 24 scientifically rigorous. They did</p>
Page 323	Page 325
<p>1 intended use, whether or not that was -- 2 the device was safe for that use. 3 In order to formulate that 4 opinion, I reviewed the highest levels of 5 evidence that I could find. As I stated 6 earlier, the highest levels of evidence 7 would include things like randomized 8 control trials, systematic reviews or 9 meta-analysis and, fortunately, there was 10 a tremendous amount of data. 11 Just right behind that would 12 be things like long-term registry 13 studies, the data that came from closed 14 health systems and the like. 15 I would add that the 16 societal guidelines position statements, 17 which are -- in essence, is a different 18 type of a committee that would have done 19 their own systematic review and then 20 formulated an opinion in the same manner. 21 Those are the type of things that I would 22 look at myself. 23 In addition, I looked at the 24 documents provided to me concerning the</p>	<p>1 not seem to include the Level 1 2 studies, randomized control 3 trials. They did not refer to the 4 systematic reviews. 5 Their focus seemed to be 6 largely on very low-level, almost 7 insignificant things that really 8 had no direct application to the 9 TVT design, safety or the device 10 when it's used in its intended 11 manner to treat stress urinary 12 incontinence. 13 BY MR. SNELL: 14 Q. So for these hernia 15 documents or hernia studies that the 16 plaintiffs' experts, like Dr. Elliott, 17 seem to cite on every page of his report, 18 would those even fit on the evidence 19 pyramid, if one was to do a proper 20 methodologic scientific review to assess 21 the safety of TVT for its intended use to 22 treat stress urinary incontinence? 23 MS. THOMPSON: Object to 24 form.</p>

82 (Pages 322 to 325)

Marc Toglia, M.D.

Page 326	Page 328
<p>1 THE WITNESS: Within the --</p> <p>2 within the context, those would</p> <p>3 not figure as well. Those would</p> <p>4 usually be discarded as being not</p> <p>5 relevant to the TVT sling, the</p> <p>6 device or its design.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. You brought these evidence</p> <p>9 pyramids.</p> <p>10 MR. SNELL: I'd like to mark</p> <p>11 them as exhibits.</p> <p>12 - - -</p> <p>13 (Whereupon, Exhibit</p> <p>14 Toglia-17, Level of Evidence</p> <p>15 Chart, was marked for</p> <p>16 identification.)</p> <p>17 - - -</p> <p>18 (Whereupon, Exhibit</p> <p>19 Toglia-18, Level of Evidence</p> <p>20 Pyramid, was marked for</p> <p>21 identification.)</p> <p>22 - - -</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Doctor, Exhibits 17 and 18,</p>	<p>1 highest levels of evidence --</p> <p>2 A. Of course.</p> <p>3 Q. -- and not just one</p> <p>4 document -- strike that.</p> <p>5 Not just one guideline or</p> <p>6 randomized control trial but numerous</p> <p>7 ones?</p> <p>8 A. We looked for consistency of</p> <p>9 the levels of evidence -- excuse me, we</p> <p>10 looked for consistency of the independent</p> <p>11 analyses that had similar levels of</p> <p>12 evidence.</p> <p>13 Q. And did you find consistency</p> <p>14 in the systematic reviews and</p> <p>15 meta-analyses that were Level 1 evidence,</p> <p>16 such as the shunt 2014 SGS study or paper</p> <p>17 and the AUA guidelines that did a</p> <p>18 systematic review?</p> <p>19 A. They're all very consistent</p> <p>20 speaking to the safety -- long-term</p> <p>21 safety, long-term effectiveness of that</p> <p>22 device.</p> <p>23 Q. On Page 18 of your report,</p> <p>24 you talk about the safety and surgical</p>
Page 327	Page 329
<p>1 are those the level of evidence pyramids</p> <p>2 you brought?</p> <p>3 A. Yes.</p> <p>4 Q. Are those important in</p> <p>5 conducting a proper -- strike that.</p> <p>6 Is utilizing the highest</p> <p>7 levels of evidence important in assessing</p> <p>8 the question, is the TVT reasonably safe</p> <p>9 for its intended use to treat stress</p> <p>10 urinary incontinence, in your opinion?</p> <p>11 A. Absolutely. I mean, the</p> <p>12 foundation of any systematic review is to</p> <p>13 start with your highest level of</p> <p>14 evidence. If you have the highest level</p> <p>15 of evidence, then the lower levels of</p> <p>16 evidence typically are not given weight.</p> <p>17 Certainly if they are</p> <p>18 incongruent -- if the lower evidence --</p> <p>19 levels of evidence are incongruent with</p> <p>20 the higher levels of evidence, it just</p> <p>21 simply validates and verifies the</p> <p>22 uselessness of those articles.</p> <p>23 Q. And I believe you testified</p> <p>24 your methodology was to look at the</p>	<p>1 re-intervention being well studied,</p> <p>2 utilizing national and regional closed</p> <p>3 systems.</p> <p>4 Do you see that at the top?</p> <p>5 A. Yes, I do.</p> <p>6 Q. That's something you were</p> <p>7 talking to the plaintiffs' counsel about,</p> <p>8 the significance of the closed systems.</p> <p>9 Do you recall that?</p> <p>10 A. Yes, I -- I started to</p> <p>11 discuss that. And the point I was trying</p> <p>12 to make is that the advantage of the --</p> <p>13 you know, certainly one of the concerns</p> <p>14 about following patients or looking for</p> <p>15 complications is, what's your degree of</p> <p>16 follow-up and whether or not those</p> <p>17 patients are somehow excluded. That's</p> <p>18 where concerns that relate to things like</p> <p>19 selection bias could come from.</p> <p>20 The advantage of looking at</p> <p>21 data, whether it's Medicare data, like</p> <p>22 the Thomson Reuters MarketScan data,</p> <p>23 Kaiser, Canada, some of the other</p> <p>24 countries, is that people, you know,</p>

83 (Pages 326 to 329)

Marc Toggia, M.D.

Page 330	Page 332
<p>1 don't drop out of the system and they are 2 able to capture, with a high degree of 3 accuracy, what happens to these 4 individuals over time.</p> <p>5 Q. And in Pages 17 through 21, 6 do you identify some of those studies 7 that you reviewed and found to be 8 scientifically reliable and high levels 9 of evidence?</p> <p>10 A. Yes, they are -- and they 11 are consistent with the Level 1 data and 12 the systematic reviews.</p> <p>13 Q. Earlier, plaintiffs' counsel 14 asked you some questions about the AUGS 15 position statement.</p> <p>16 Do you recall that in 17 general?</p> <p>18 A. Yes.</p> <p>19 Q. Can you turn to that? I 20 just have a few follow-up questions. I 21 believe it was in one of these multiple 22 binders.</p> <p>23 A. Less than one minute, sir, I 24 have it right in front of me.</p>	<p>1 provided, and I would point out that the 2 references cited do consist of 3 high-quality levels of evidence, which 4 talks about the fact that -- that this 5 particular procedure had been studied as 6 long in follow up than any other 7 procedure and seems to demonstrate 8 superior safety and efficacy.</p> <p>9 Q. If you look at Reference 10 Number 8, under Paragraph 1, where it 11 talks about the lightweight monofilament 12 polypropylene sling has demonstrated 13 long-term durability, safety and efficacy 14 for up to 17 years, are they referring to 15 the Ethicon TVT Retropubic sling that 16 assessed?</p> <p>17 A. Yes. That refers to the 18 Nielsen long-term prospective cohort 19 that, I believe, looked at, over a 20 17-year period of time, a group of 21 approximately 90 individuals.</p> <p>22 Q. Does that AUGS/SUFU position 23 statement, is it reliant upon Level 1 24 evidence like Cochrane reviews or</p>
Page 331	Page 333
<p>1 Oh, I have to apologize. 2 Okay.</p> <p>3 Q. Remember plaintiffs' counsel 4 asked you some questions about the 5 AUGS/SUFU position statement and whether 6 it had any discussion about safety or 7 complications?</p> <p>8 A. Yes.</p> <p>9 Q. Take a look at Paragraph 10 Number 2.</p> <p>11 Does the AUGS/SUFU statement 12 have any discussion about an assessment 13 of whether the TVT or midurethral sling 14 is safe?</p> <p>15 Sorry, numbered Paragraph 2, 16 unless I'm --</p> <p>17 A. Numbered paragraph. Oh, I'm 18 sorry.</p> <p>19 Number 2 which starts, The 20 monofilament polypropylene mesh is the 21 most extensively studied 22 anti-incontinence procedure in history.</p> <p>23 So, yes, this particular 24 paragraph -- and the references are</p>	<p>1 randomized control trials?</p> <p>2 A. Yes, it is.</p> <p>3 Q. One of the end notes in the 4 overall assessment of the slings is 5 Cochrane review by Ogah, et al.</p> <p>6 A. Yes.</p> <p>7 Q. Is that a study that you're 8 familiar with?</p> <p>9 A. It is. But that's a 10 meta-analysis.</p> <p>11 Q. And what is the significance 12 of that type of meta-analysis and being a 13 Cochrane review, if anything?</p> <p>14 A. Sure. So a meta-analysis 15 seeks to look at as much of the relevant 16 literature. As well, it will -- it will 17 take all of the randomized control 18 trials, it will sort of combine the data, 19 in a sense, for analysis. It will draw 20 comparisons to the other procedures or 21 the other approaches.</p> <p>22 Q. Okay. And do those 23 references that the AUGS/SUFU position 24 statement rely upon for the statements in</p>

84 (Pages 330 to 333)

Marc Toggia, M.D.

Page 334	Page 336
<p>1 that assess the complications with TVT?</p> <p>2 A. Yes.</p> <p>3 Q. Such that -- and I believe</p> <p>4 you talk about, in the Ogah study, in</p> <p>5 your report, you discuss that that</p> <p>6 Cochrane review discusses multiple</p> <p>7 complications?</p> <p>8 A. It does.</p> <p>9 Q. Including that the</p> <p>10 monofilament and macroporous mesh, like</p> <p>11 TVT Retropubic, in the treatment of</p> <p>12 stress urinary incontinence has a lower</p> <p>13 rate of exposure than the multifilament</p> <p>14 meshes.</p> <p>15 Do you recall that from the</p> <p>16 Ogah Cochrane review?</p> <p>17 A. Yes. And I believe that the</p> <p>18 majority of the studies that were</p> <p>19 included in that analyses would have been</p> <p>20 specifically with the Retropubic TVT</p> <p>21 device.</p> <p>22 Although, there was another</p> <p>23 part of the analysis that would have</p> <p>24 looked at the Obturator approach as</p>	<p>1 Q. -- to look for that.</p> <p>2 My question to you is this:</p> <p>3 Did you track your patients' complication</p> <p>4 rates over time with the TVT Retropubic</p> <p>5 device?</p> <p>6 A. Yes, we did.</p> <p>7 Q. How did you do that?</p> <p>8 A. We kept notes on the</p> <p>9 patients. I mean, most -- you know, when</p> <p>10 you're dealing with a procedure that, in</p> <p>11 our hands, had complication rates in the</p> <p>12 single digits, it's not that hard to make</p> <p>13 the mental note, you know, that, you</p> <p>14 know, we saw two episodes of bleeding</p> <p>15 that required observation.</p> <p>16 Q. Did you counsel your</p> <p>17 patients on your rates of complications</p> <p>18 you had with the TVT Retropubic device</p> <p>19 over time as you gained experience?</p> <p>20 A. Yes. I felt an obligation,</p> <p>21 certainly, as somebody that was well</p> <p>22 respected in this field and somebody that</p> <p>23 was able to offer several different</p> <p>24 options to my patients in this, that we</p>
Page 335	Page 337
<p>1 compared to the Retropubic approach.</p> <p>2 Q. Considering that this</p> <p>3 AUGS/SUFU position statement, as you have</p> <p>4 testified, relies on Level 1 systematic</p> <p>5 reviews and other data, do you believe it</p> <p>6 is reliable?</p> <p>7 A. Absolutely.</p> <p>8 Q. Some questions were asked to</p> <p>9 you -- strike that.</p> <p>10 And do you believe that the</p> <p>11 other position statements and the stress</p> <p>12 urinary incontinence systematic reviews</p> <p>13 and guidelines by SGS, the American</p> <p>14 Urologic Association, IUGA, and others,</p> <p>15 are also reliable?</p> <p>16 A. They are -- they are</p> <p>17 reliable and they're incredibly</p> <p>18 consistent with each other.</p> <p>19 Q. You were asked some</p> <p>20 questions about complications your</p> <p>21 patients may have had and how plaintiffs'</p> <p>22 counsel, what documents she would go</p> <p>23 to --</p> <p>24 A. Sure.</p>	<p>1 would talk to them, again, sort of about</p> <p>2 our personal experience.</p> <p>3 You know, when you -- when</p> <p>4 you work out in the community and you</p> <p>5 take care of women in the community and</p> <p>6 you're not necessarily at a university</p> <p>7 hospital, I have found that women are</p> <p>8 very much interested in what your</p> <p>9 personal experience was.</p> <p>10 Obviously, we were very</p> <p>11 fortunate to have a high volume of cases.</p> <p>12 And within that context, I could say to</p> <p>13 them, you know, regularly, look, I've</p> <p>14 done 500 of these and, you know, the</p> <p>15 complications that we have seen are --</p> <p>16 you know, there have been occasional</p> <p>17 episodes of bleeding from time to time,</p> <p>18 either during or after the procedure,</p> <p>19 things of that nature.</p> <p>20 Q. And so when you put in your</p> <p>21 report, for example, your complication</p> <p>22 rates, in your hands and -- for example,</p> <p>23 that your rate of bladder perforation</p> <p>24 with the TVT Retropubic decreased over</p>

85 (Pages 334 to 337)

Marc Toggia, M.D.

Page 338	Page 340
<p>1 time as you became more experienced, are</p> <p>2 those reliable rates?</p> <p>3 A. Yes.</p> <p>4 Q. Are those based on your</p> <p>5 firsthand observations and tracking of</p> <p>6 your complication rates over time with</p> <p>7 the TVT Retropubic device?</p> <p>8 A. They are.</p> <p>9 Q. You talked to plaintiffs'</p> <p>10 counsel about your various different</p> <p>11 design expertise and work you did with</p> <p>12 Ethicon on many different products.</p> <p>13 Do you recall that?</p> <p>14 A. I do.</p> <p>15 Q. One thing I want to ask you</p> <p>16 about, I didn't recall if you said it or</p> <p>17 not, but do you recall the GYNEMESH® M,</p> <p>18 the ULTRAPRO™ mesh product that was used</p> <p>19 in PROLIFT®?</p> <p>20 A. I do.</p> <p>21 Q. Do you recall --</p> <p>22 A. That was used, excuse me, in</p> <p>23 PROLIFT® +M.</p> <p>24 Q. PROLIFT® +M. Thank you for</p>	<p>1 exposures or wound complications with the</p> <p>2 Burch.</p> <p>3 I want to hand you the</p> <p>4 Schimpf paper.</p> <p>5 And, actually, first of all,</p> <p>6 do you have your report handy?</p> <p>7 A. I do.</p> <p>8 Q. Turn to Page 19, on the</p> <p>9 second paragraph, where you discuss wound</p> <p>10 complications occurring with the Burch</p> <p>11 and autologous fascial sling.</p> <p>12 Do you see that?</p> <p>13 A. The -- you're referring to</p> <p>14 Novara, et al.?</p> <p>15 Q. I'm right here on Page 19?</p> <p>16 A. I'm sorry. Yes.</p> <p>17 Q. So in the Schimpf -- I put</p> <p>18 before you the Schimpf SGS systematic</p> <p>19 review and meta-analysis.</p> <p>20 Is that a document you're</p> <p>21 familiar with?</p> <p>22 A. Yes, it is.</p> <p>23 Q. Is that a document you</p> <p>24 reviewed and rely upon?</p>
Page 339	Page 341
<p>1 your correction.</p> <p>2 A. Sure.</p> <p>3 Q. Do you recall that you were</p> <p>4 actually one of the surgeons that did the</p> <p>5 design validation of the GYNEMESH® M</p> <p>6 mesh, assessing the suitability, safety</p> <p>7 and efficacy and adequacy of that design?</p> <p>8 A. I did participate in some</p> <p>9 kind of a design validation study, yes.</p> <p>10 Q. Do you recall assessing the</p> <p>11 IFU for that device during the design</p> <p>12 validation?</p> <p>13 A. Yes, I do.</p> <p>14 Q. And whether you were asked,</p> <p>15 is the IFU, clear, cohesive, accurate, do</p> <p>16 you recall that?</p> <p>17 A. Yes.</p> <p>18 Q. And did you give opinions to</p> <p>19 Ethicon in that design validation for the</p> <p>20 GYNEMESH® M device?</p> <p>21 A. I provided them with, you</p> <p>22 know, constructive feedback.</p> <p>23 Q. Some questions were asked of</p> <p>24 you, I think, about pubovaginal sling</p>	<p>1 A. Yes, it is.</p> <p>2 Q. Is that a document that's</p> <p>3 reliable, in your opinion, to</p> <p>4 scientifically assess the safety and</p> <p>5 utility of the design of the TVT</p> <p>6 Retropubic device?</p> <p>7 A. It's a very reliable</p> <p>8 device -- very reliable document.</p> <p>9 This is what -- this is what</p> <p>10 we were speaking to Level 1 evidence.</p> <p>11 This is a systematic review -- an</p> <p>12 independent systematic review.</p> <p>13 Q. And the Society of</p> <p>14 Gynecologic Surgeons, do they have a good</p> <p>15 reputation within the field of female</p> <p>16 pelvic medicine?</p> <p>17 A. Absolutely.</p> <p>18 Q. Do you actually belong to</p> <p>19 that society?</p> <p>20 A. I serve a leadership role.</p> <p>21 I serve on the executive committee for</p> <p>22 that society.</p> <p>23 Q. And in your role and</p> <p>24 participation with the society -- let me</p>

86 (Pages 338 to 341)

Marc Toggia, M.D.

Page 342	Page 344
<p>1 ask you this: Before I contacted you and</p> <p>2 asked you to analyze the data, had you</p> <p>3 already been reviewing and analyzing data</p> <p>4 on the TVT Retropubic device?</p> <p>5 A. Yes.</p> <p>6 Q. Had you been reviewing data</p> <p>7 and analyzing data, the different levels</p> <p>8 of data, on the TVT Retropubic device</p> <p>9 going back all the way to when you began</p> <p>10 considering to use it?</p> <p>11 A. Yes. Absolutely.</p> <p>12 Q. So let's look at the Schimpf</p> <p>13 systematic review and meta-analysis.</p> <p>14 Does that study -- strike</p> <p>15 that.</p> <p>16 Looking at the Schimpf</p> <p>17 systematic review -- review and</p> <p>18 meta-analysis, does that Level 1</p> <p>19 systematic review inform you of wound</p> <p>20 complications and other problems that can</p> <p>21 occur with the Burch and the pubovaginal</p> <p>22 sling?</p> <p>23 A. It does.</p> <p>24 Q. In the table in the Schimpf</p>	<p>1 It also looked at return to</p> <p>2 the operating room specifically to</p> <p>3 treat -- to treat erosions as well. It</p> <p>4 looked at wound infections, hematoma,</p> <p>5 dyspareunia, various organ injuries.</p> <p>6 Q. Did -- did that inform your</p> <p>7 opinions on the safety of the TVT device</p> <p>8 for the intended use of the treatment of</p> <p>9 stress urinary incontinence?</p> <p>10 A. Yes. And, obviously, as you</p> <p>11 can imagine, I was very reassured by the</p> <p>12 fact that it was both consistent with my</p> <p>13 experience, having performed, you know,</p> <p>14 each of these procedures, and also</p> <p>15 confirmed my experience and my own review</p> <p>16 of the literature of the safety and</p> <p>17 long-term efficacy of this procedure.</p> <p>18 Q. You mentioned earlier that</p> <p>19 there was consistency in the Level 1 data</p> <p>20 and the longer-term studies, the</p> <p>21 prospective database studies.</p> <p>22 Why is that important in</p> <p>23 conducting a proper scientific</p> <p>24 methodologic analysis of the question, is</p>
Page 343	Page 345
<p>1 paper, does it identify whether patients</p> <p>2 with pubovaginal sling or Burch have</p> <p>3 wound infections, exposure and return to</p> <p>4 the operating room for erosions?</p> <p>5 A. Yes. Table 3, specifically,</p> <p>6 addresses the analysis that would look</p> <p>7 at -- and, again, this was exclusive</p> <p>8 of -- excuse me, this was inclusive of</p> <p>9 randomized control trials.</p> <p>10 So this is a -- this is a</p> <p>11 summary of the analysis of Level 1 data.</p> <p>12 Q. And did the Schimpf</p> <p>13 systematic review, the summary of Level 1</p> <p>14 data, identify that the Burch and the</p> <p>15 pubovaginal sling had exposures or return</p> <p>16 to the operating room for erosion?</p> <p>17 A. Yes.</p> <p>18 Q. Did -- go ahead. I'm sorry.</p> <p>19 A. So, specifically, it</p> <p>20 analyzed the number of studies and the</p> <p>21 incidence of, say, exposure between three</p> <p>22 different types of midurethral slings,</p> <p>23 the traditional, pubovaginal vaginal and</p> <p>24 the Burch.</p>	<p>1 the TVT safe for its intended use to</p> <p>2 treat stress urinary incontinence?</p> <p>3 A. Well, objectivity. You</p> <p>4 know, the reasons why one designs a</p> <p>5 randomized control trial is that we're</p> <p>6 trying to eliminate everything from</p> <p>7 selection bias, having patients that</p> <p>8 might be sicker in one arm versus the</p> <p>9 other, more comorbid conditions,</p> <p>10 variations that might relate individually</p> <p>11 to a certain -- a particular surgeon or</p> <p>12 institution.</p> <p>13 Q. Plaintiffs' counsel asked</p> <p>14 you about degradation, and I believe you</p> <p>15 told her, numerous times, that you didn't</p> <p>16 believe that the TVT degraded; is that</p> <p>17 correct or not?</p> <p>18 A. Within the clinical use of</p> <p>19 the TVT for the treatment of stress</p> <p>20 urinary incontinence, there -- I'm not</p> <p>21 aware of any reliable data suggesting</p> <p>22 that there is degradation.</p> <p>23 Q. The plaintiffs' counsel</p> <p>24 asked you a question about were there any</p>

87 (Pages 342 to 345)

Marc Toggia, M.D.

Page 346	Page 348
<p>1 studies that -- I think the question was, 2 and it may have been a double negative -- 3 that did not show oxidative degradation. 4 Do you recall questioning on 5 that? 6 A. I do. And the more that I 7 thought about it, I realized that I did 8 address that in my report. 9 Q. Can you turn to Page 26 of 10 your report? 11 A. Yes. 12 Q. There was a paper that the 13 plaintiffs' experts pointed to by Clave. 14 Do you -- have you read that 15 paper? 16 A. I'm familiar with that 17 study. 18 Q. And, first of all, is that 19 study a reliable study to assess, 20 scientifically, the TVT and, in 21 particular, for its intended use to treat 22 stress urinary incontinence? 23 A. I mean, I don't believe that 24 the Clave study looked specifically at</p>	<p>1 limitations and the poor methodology in 2 the Clave study, did they document that 3 they can show oxidation of the 4 polypropylene? 5 A. They comment directly upon 6 that. Again, you know, oxidative 7 degradation is a chemical reaction 8 typically reserved for enzymatic changes 9 to, say, amino acids. 10 Again, as I think I stated 11 earlier, it simply involves the insertion 12 of oxygen between carbon -- you know, 13 between carbon molecules within a 14 compound. In that concept, you know, 15 polypropylene is not an amino acid or an 16 organic compound. 17 But the authors do very 18 specifically state that they were very 19 limited in how they could respond to 20 here -- they say -- they say here that, 21 you know, look, we have to acknowledge 22 that while we offer an opinion -- we 23 offer hypotheses that, maybe, what we're 24 seeing in terms of changes could be the</p>
Page 347	Page 349
<p>1 the TVT device, per se. So it was a 2 low-level observational study, in vitro, 3 in a sense, in that the -- in that the 4 material was analyzed under a scanning 5 electron microgram and some chemical 6 analysis. 7 Q. And I believe you earlier 8 testified, for the intended use of 9 treating stress urinary incontinence, is 10 Clave one of the studies that wouldn't 11 even make it onto the level of evidence 12 pyramid because it doesn't specifically 13 focus on the intended treatment of stress 14 incontinence? 15 A. I don't believe that Clave 16 would be considered in that kind of 17 high-level evidence analysis, in terms of 18 the clinical utility, safety or design of 19 that device. 20 Q. So back to my earlier -- the 21 reason why I brought you to this study or 22 asked you about it, plaintiffs' counsel 23 asked you about direct oxidation. 24 Even with all the</p>	<p>1 result of oxidation. They said, look, we 2 can't confirm this hypothesis, based upon 3 our methodology or our analysis, whether 4 or not direct oxidation would actually 5 have occurred in vivo. 6 Q. So you saw they did some 7 analytical chemistry testing on a limited 8 number of samples in the Clave paper, and 9 even with that methodology, they were 10 unable to confirm their hypothesis; is 11 that right? 12 MS. THOMPSON: Object to 13 form. 14 THE WITNESS: Again, you 15 know, they -- the way that Clave 16 was set up is they looked under -- 17 under a scanning electron 18 microscope, very, very high power. 19 You know, here is the pristine 20 material, here are these -- these 21 expanded small fragments of 22 material. 23 In that paper, if I'm -- if 24 I'm correct, their only definition</p>

88 (Pages 346 to 349)

Marc Toggia, M.D.

Page 350	Page 352
<p>1 of degradation is this doesn't 2 look like this. 3 And, you know -- and they 4 did not see changes in all 5 specimens. In fact, they saw 6 changes only in a minority of 7 those implants analyzed. And, you 8 know, again, you know, they said, 9 look, we acknowledge that we 10 cannot determine whether what we 11 observed somehow altered 12 mechanical properties. They 13 acknowledge that they could not 14 analyze implants that were in 15 women that had not gone back to 16 the operating room to have a 17 portion removed for some clinical 18 indication. 19 And, certainly, my opinion 20 would follow that as well, simply 21 the observation of surface crack, 22 the minority of specimen does not 23 establish that degradation does 24 occur.</p>	<p>1 I guess my question for you 2 is, at Page 266, you had mentioned that 3 the authors acknowledged that what they 4 were doing was basically hypothesizing; 5 is that correct? 6 A. Well, I mean, you know, the 7 authors did make an observation that the 8 material had a different external 9 appearance, albeit under only, you know, 10 very high powered scanning electron 11 microscopy. And then they start to come 12 up with some ideas that might potentially 13 explain it. 14 And they said, look, you 15 know, we've talked about several 16 hypotheses concerning whether or not, you 17 know, this represents degradation. 18 Again, their definition of degradation 19 is, this doesn't look exactly the same as 20 the pristine state. 21 And they say, you know, none 22 of these hypotheses, particularly they 23 point out the hypotheses of oxidation, 24 could possibly be confirmed in this</p>
Page 351	Page 353
<p>1 And, again, as I've stated 2 over and over, you know, that it's 3 unlikely that this could have any 4 kind of mechanical or functional 5 outcome. But, more importantly 6 is, again, you simply can't infer. 7 You can't clinically infer from a 8 paper such as this, which is just 9 sort of an observation to any kind 10 of effect that it might have when 11 it's used for its typical 12 indication. 13 BY MR. SNELL: 14 Q. And with regard to the 15 oxidation question, looking at the 16 article, at the bottom of Page 266, it 17 states, Several hypotheses concerning 18 degradation of polypropylene are 19 described below. None of these -- 20 A. Counselor, I'm sorry, I'd 21 like to follow along with you. 22 Q. I'm sorry. 23 A. I'm sorry. Go ahead. 24 Q. You can just take it.</p>	<p>1 study. 2 Q. You were asked some 3 questions about whether there is an 4 immunologic reaction, whether there's 5 severe chronic inflammation -- you were 6 asked some questions, Doctor, about 7 whether there was immunologic reaction to 8 the TVT polypropylene mesh device. 9 And I believe one of the 10 things you stated was that the randomized 11 control trials, the Level 1 evidence, the 12 long-term data do not show any type of 13 immunologic response in your opinion. 14 Is that correct or did I 15 misstate that? 16 A. No, the majority of the 17 studies, the five-year data and ten-year 18 data, you know, where they said, look, we 19 did not observe one instance of clinical 20 inflammation, chronic inflammation, 21 erosion, you know, that speaks to the 22 safety and the lack of a significant 23 adverse immunologic reaction. 24 And, again, I think just --</p>

89 (Pages 350 to 353)

Marc Toggia, M.D.

Page 354	Page 356
<p>1 as a scientist, as a surgeon, what I 2 would speak to distinguish between are, 3 you know, reactions that the body has 4 that are of no clinical consequence, 5 reactions that the body has that could 6 result in an adverse clinical outcome. 7 Q. Do you have Dr. Rosenzweig's 8 binder over there somewhere? 9 A. In my left hand, I have his 10 expert report. Below me, we have a 11 binder labeled, Company Documents, 12 Rosenzweig. 13 Q. Let me -- Doctor, if you go 14 back to the middle of -- I know you have 15 a lot of materials in front of you. But 16 go back to the pile. Under -- I think 17 it's under your report, where you were 18 looking at the Schimpf paper as one of 19 the exhibits. Here. 20 Can I take a look at that, 21 Doctor? 22 Let me ask you this: Do you 23 remember, you were asked a question about 24 the Wang study by the plaintiffs'</p>	<p>1 typical case controlled study is a Level 2 3. 3 Now, what's incumbent upon a 4 case controlled study is that you have a 5 very appropriate control group for that 6 study. And the reason for that is that 7 you're trying to minimize selection bias 8 and other forms of bias that could be 9 introduced. And so, as an investigator, 10 you have to be sure that you're picking a 11 group that is representative of your 12 control. 13 If one group has a certain 14 outcome and you're trying to look at the 15 cause for that outcome, the other group 16 needs to have similar exposure but not 17 the outcome. 18 So, for example, everyone 19 has a sling, the control group has a 20 sling with -- but lacks the particular 21 adverse outcome you're looking for, 22 whereas the affected group has that 23 outcome, itching, let's say, okay? 24 Unfortunately, for some</p>
Page 355	Page 357
<p>1 counsel, if you read it and its 2 methodology. 3 Do you recall that? 4 A. I have the Wang study here. 5 Q. Okay. And you were going to 6 try to answer plaintiffs' counsel's -- 7 strike that. 8 You wanted to make a 9 statement or give your impression of the 10 methodology of the Wang paper; is that 11 correct? 12 A. Yes. I offered an opinion, 13 and I wanted to explain my methodology. 14 Q. Please go ahead and do that. 15 A. Wang published a -- we would 16 consider -- I mean, he calls this a 17 prospective case-controlled pilot study. 18 Now, you know, within the 19 world of study design, you know, case 20 controlled studies are, by definition, 21 retrospective, not prospective. Again, 22 case controlled studies are a much lower 23 level of evidence. If we look at the 24 information that I provided here, a</p>	<p>1 reason, the investigators chose a control 2 group that consisted of only about seven 3 women. And, again, this was a study of 4 700 women that had undergone a procedure. 5 And these were not -- these were not 6 control women, these were women that did 7 have a clinical problem that would 8 involve a removal of the portion of the 9 mesh so it could be compared. But that's 10 not an appropriate control group. 11 So I look at this study and 12 say, you know, in all fairness, this is a 13 case series as opposed to a case 14 controlled. And, you know, that does 15 knock down the level of evidence from a 3 16 to, actually, now a Case 4. 17 And, again, the reason why I 18 make that determination is that, you 19 know, we're trying to determine whether 20 or not we can infer clinical outcome, 21 clinical importance. And, again, as we 22 go down on the scale of evidence, you 23 cannot make that inference. 24 Q. And in that study, because</p>

90 (Pages 354 to 357)

Marc Toggia, M.D.

<p style="text-align: right;">Page 358</p> <p>1 of the limitations of that study, can you 2 make that inference with the Wang study? 3 A. No. You can't make that 4 inference with the Wang study. 5 Q. Does a study like the Wang 6 study provide scientifically reliable 7 information on the rate of the 8 complication -- I'm sorry, the incidence 9 of complication? 10 A. Sure. So that's the other 11 thing that -- that, you know, a 12 well-schooled academician would tell you, 13 is that you don't calculate prevalence or 14 incidence based upon a case-controlled 15 study. 16 Q. And for the case series, 17 like the Abbott paper that plaintiffs' 18 counsel asked you about earlier, do those 19 also allow someone to scientifically 20 reliably speak to what the incidence of a 21 complication is? 22 A. In the Abbott trial, I think 23 the authors correctly pointed out that, 24 because they could not place a</p>	<p style="text-align: right;">Page 360</p> <p>1 fascial sling. 2 Are either one of those 3 medical devices? 4 A. They are not medical 5 devices, they are surgical techniques. 6 Q. So the Burch and autologous 7 fascial sling are not alternative devices 8 to the TVT, which is a device? 9 A. They are not alternative 10 devices to the TVT. 11 Q. You were asked questions and 12 shown an MSDS, material safety data 13 sheet, on bulk polypropylene. 14 A. Yes. 15 Q. Is that MSDS sheet relevant 16 or clinically scientifically reliable to 17 assess whether the TVT Retropubic device 18 is reasonably safe for its intended use 19 to treat stress urinary incontinence? 20 A. No. That would be a 21 conclusion that you would get based 22 solely on your Level 1 levels of 23 evidence. 24 Q. Would the MSDS sheet even be</p>
<p style="text-align: right;">Page 359</p> <p>1 denominator, that you could not really 2 speak to incidence. 3 Q. Do the systematic reviews, 4 meta-analyses, numerous five-plus year 5 data that you referenced show consistency 6 in the overall safety and efficacy of 7 TVT? 8 A. They do. 9 Q. You earlier mentioned that 10 all of -- all of that data, and you cited 11 hundreds of different papers, I believe, 12 in your report, shows that the PROLENE® 13 polypropylene Type I macroporous mesh in 14 TVT for the intended use to treat stress 15 incontinence is the most biocompatible. 16 What did you mean by that? 17 A. Biocompatible, you know, 18 sort of a synonym for that, you would say 19 it shows good host tolerability. That it 20 was capability of existing within host 21 tissue with minimal to no adverse 22 reaction. 23 Q. You were asked questions 24 about the Burch and the autologous</p>	<p style="text-align: right;">Page 361</p> <p>1 on the levels of evidence? 2 A. They would not. 3 Q. You made -- you were asked 4 questions about cancer, sarcoma. 5 Do you recall that? 6 A. I do recall that. I do 7 believe that I addressed that in my 8 report. 9 Q. At Pages 25 and 26, it looks 10 like you addressed those issues; is that 11 correct? At the bottom of 25? 12 A. Yes. 13 Q. And in the MSDS sheet, it 14 talked about sarcomas in rats where the 15 polypropylene was in disc or powder form. 16 Do you recall that? 17 A. Yes, I do. 18 Q. And you made a statement 19 about how those data are not pertinent or 20 relevant to the TVT in its configuration 21 to treat stress urinary incontinence as a 22 knitted macroporous mesh? 23 A. Yeah. The point that I was 24 trying to make, and I don't think I</p>

91 (Pages 358 to 361)

Marc Toggia, M.D.

Page 362	Page 364
<p>1 stated it very eloquently, is that the</p> <p>2 investigations that have looked into such</p> <p>3 claims had focused on the fact that it's</p> <p>4 really the material composition, it's not</p> <p>5 polypropylene, per se, but the composite</p> <p>6 material.</p> <p>7 And additional studies were</p> <p>8 done, following those initial ones, that</p> <p>9 showed, really, no risk of sarcoma</p> <p>10 formation.</p> <p>11 I mean, again, as a</p> <p>12 physician and scientist, these concerns</p> <p>13 have been addressed by my peers.</p> <p>14 There's -- number one, to the best of my</p> <p>15 knowledge, there's never been a reported</p> <p>16 case of a sarcoma occurring in a patient</p> <p>17 with a TVT.</p> <p>18 As I stated that, you know,</p> <p>19 polypropylene has been a material of</p> <p>20 choice for 40 to 50 years. And in that</p> <p>21 context, there are no cases in women.</p> <p>22 And my opinion was that, you know,</p> <p>23 concerns about potential carcinogenesis</p> <p>24 in women really are not substantiated,</p>	<p>1 MS. THOMPSON: Object to</p> <p>2 form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MR. SNELL:</p> <p>5 Q. Doctor, have you seen</p> <p>6 that -- have you seen testing like that?</p> <p>7 A. I've seen the reports on the</p> <p>8 testing like that.</p> <p>9 Q. And photographs like the</p> <p>10 photographs in Dr. Elliott or</p> <p>11 Rosenzweig's report, where he put in</p> <p>12 there a piece of mesh that was clamped</p> <p>13 and it didn't have a sheath or any</p> <p>14 instruments.</p> <p>15 Do you recall that?</p> <p>16 A. Yes.</p> <p>17 Q. All right. My question to</p> <p>18 you is, is that photo and the testing of</p> <p>19 the mesh in that manner scientifically</p> <p>20 reliably pertinent to the use of TVT and,</p> <p>21 in particular, its safety in the intended</p> <p>22 treatment --</p> <p>23 A. It's out --</p> <p>24 Q. -- of stress urinary</p>
Page 363	Page 365
<p>1 based upon this clinical experience and</p> <p>2 the established literature.</p> <p>3 Q. And you cite to a paper by</p> <p>4 King and Goldman, where they did an</p> <p>5 analysis of the Cleveland Clinic's use of</p> <p>6 thousands of slings over a long period of</p> <p>7 time.</p> <p>8 Do you recall that?</p> <p>9 A. I recall that paper.</p> <p>10 Q. Was that one of the papers</p> <p>11 you relied upon for your conclusion that</p> <p>12 the TVT PROLENE® polypropylene</p> <p>13 macroporous Type I mesh does not cause</p> <p>14 cancer or sarcoma in its intended use to</p> <p>15 treat stress urinary incontinence?</p> <p>16 A. That's correct.</p> <p>17 Q. Plaintiffs' counsel asked</p> <p>18 you questions about roping and curling</p> <p>19 and the mechanical testing of the mesh.</p> <p>20 Let me ask you, you -- I</p> <p>21 think you told plaintiffs' counsel this,</p> <p>22 you've seen the testing where they put</p> <p>23 the TVT -- or they put some kind of mesh</p> <p>24 on a bench machine and stretched it?</p>	<p>1 incontinence?</p> <p>2 A. I mean, it's outside the</p> <p>3 intended use. So, no, it's not relevant.</p> <p>4 And, as I stated, you know,</p> <p>5 the mesh is delivered protected beneath</p> <p>6 the -- a sheath. Those forces are not</p> <p>7 directly exerted on the mesh itself.</p> <p>8 Q. And is that --</p> <p>9 A. But it's specific to the</p> <p>10 tension-free design, which is where the</p> <p>11 name TVT comes from, tension-free vaginal</p> <p>12 tape. And that speaks to the design and</p> <p>13 the method in which it's placed.</p> <p>14 Q. And in your report, I</p> <p>15 believe you talk about the importance in</p> <p>16 the design characteristics of the sheath</p> <p>17 and what it does?</p> <p>18 A. Sure. I mean, that was very</p> <p>19 important in the design.</p> <p>20 And I would point out</p> <p>21 that's, you know, -- subsequent</p> <p>22 developments along the area of</p> <p>23 anti-incontinence procedures all pretty</p> <p>24 much kept that element of the design</p>

Marc Toggia, M.D.

Page 366	Page 368
<p>1 intact.</p> <p>2 Q. And you had mentioned the</p> <p>3 sheath was important, very important, in</p> <p>4 your opinion to plaintiffs' counsel; is</p> <p>5 that correct?</p> <p>6 A. Yes.</p> <p>7 Q. Why -- so is the sheath a</p> <p>8 very important design element of the TVT</p> <p>9 for its intended use to treat stress</p> <p>10 urinary incontinence?</p> <p>11 A. It's elemental in the</p> <p>12 design. Without the sheath, you would</p> <p>13 not have a TVT device.</p> <p>14 Q. Okay. And having placed,</p> <p>15 you know, well over 1,000 TVT Retropublic</p> <p>16 devices, did you find the sheath to be</p> <p>17 integral or elemental in the use of that</p> <p>18 device to treat stress incontinence as</p> <p>19 you were utilizing it?</p> <p>20 A. Yes. You know, again, the</p> <p>21 sheath provided several key elements.</p> <p>22 One is that it protected the sheath from</p> <p>23 exposure to the surrounding tissue, to</p> <p>24 bacteria.</p>	<p>1 with the articles in which</p> <p>2 portions of mesh, we'll call them</p> <p>3 sheathless mesh, mesh without</p> <p>4 sheath, were applied in those</p> <p>5 applications.</p> <p>6 BY MR. SNELL:</p> <p>7 Q. Those types of documents and</p> <p>8 that -- I'll call it data or information</p> <p>9 the plaintiffs' experts relied on, do you</p> <p>10 find that information scientifically</p> <p>11 reliable for assessing the question, is</p> <p>12 the TVT suitable or reasonably safe for</p> <p>13 its intended use --</p> <p>14 A. It's certainly</p> <p>15 not clinically relevant --</p> <p>16 Q. -- to treat stress urinary</p> <p>17 incontinence?</p> <p>18 A. -- to the design of the TVT</p> <p>19 as it's used for its intended use, no.</p> <p>20 MR. SNELL: Let's go off the</p> <p>21 record. Let me see. I think I</p> <p>22 may be done.</p> <p>23 VIDEO TECHNICIAN: We are</p> <p>24 off the record. The time is 9:05</p>
Page 367	Page 369
<p>1 But I think that, you know,</p> <p>2 certainly, its greatest utility was to</p> <p>3 prevent the sheath from changing its</p> <p>4 configuration.</p> <p>5 Q. Plaintiffs' counsel asked</p> <p>6 you a bunch of hypothetical questions</p> <p>7 about pore were collapse and curling and</p> <p>8 fraying and things like that.</p> <p>9 You recall seeing those</p> <p>10 terms mentioned in the plaintiffs' expert</p> <p>11 reports?</p> <p>12 MS. THOMPSON: Object to</p> <p>13 form.</p> <p>14 THE WITNESS: Yes, I do.</p> <p>15 BY MR. SNELL:</p> <p>16 Q. You saw where Dr. Elliott,</p> <p>17 and others, would cite to some paper by</p> <p>18 Dr. Klinge in a hernia application or a</p> <p>19 rabbit or a mouse study, different data</p> <p>20 for those theories they were espousing,</p> <p>21 correct?</p> <p>22 MS. THOMPSON: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: I'm familiar</p>	<p>1 p.m.</p> <p>2 - - -</p> <p>3 (Whereupon, a discussion off</p> <p>4 the record occurred.)</p> <p>5 - - -</p> <p>6 VIDEO TECHNICIAN: We are</p> <p>7 back on the record.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. And I believe, per your</p> <p>10 earlier testimony, Doctor, those animal</p> <p>11 studies or hernia studies, or documents,</p> <p>12 are not even on the level of evidence if</p> <p>13 we were trying to look to scientifically</p> <p>14 reliable relevant evidence to the</p> <p>15 application of treating stress</p> <p>16 incontinence; is that correct?</p> <p>17 A. They are -- you are correct.</p> <p>18 And they certainly don't speak to the</p> <p>19 safety of the procedure.</p> <p>20 Q. Last question.</p> <p>21 Do you have Exhibit 4?</p> <p>22 Plaintiffs' counsel asked you some</p> <p>23 questions about this e-mail with Kathleen</p> <p>24 Feeney, and she insinuated that there</p>

93 (Pages 366 to 369)

Marc Toglia, M.D.

Page 370	Page 372
<p>1 was -- the statement -- here I'll give it 2 to you. 3 A. Thank you. 4 Q. -- "can you do her 5 downstairs" had to do with some type of 6 sexual interaction. 7 MS. THOMPSON: Object to 8 form. That's not what I 9 insinuated. 10 BY MR. SNELL: 11 Q. Can you tell, having had 12 time to look and think about this -- 13 A. Sure. 14 Q. Tell us what, if anything, 15 you believe this pertains to. 16 A. So Kathleen Feeney had 17 referred either friends of hers, or 18 someone, when they found out what they 19 did for a living, might say, you know, 20 I'm a woman who suffers with stress 21 incontinence, I know you're in this 22 field, what -- which of your doctors 23 would you recommend that I see. She 24 would -- she would give my name and</p>	<p>1 might have responded, I can do you 2 downstairs. 3 Now, to the best of my 4 recollection, Kathleen Feeney had two 5 children of her own. I may have teased 6 her from time to time, that, so, hey, you 7 know you're going to need a sling, right? 8 So who are you going to have, you know, 9 do your sling? And she would say, gee, I 10 don't know, Dr. Toglia, I might have you 11 do me, or I might have Dr. So-and-so do 12 me, again, in references to doing her 13 sling. 14 Q. Did you feel harassed when 15 you were asked those questions by 16 plaintiffs' counsel? 17 A. I was very much harassed. 18 And I tried to do my best to stay as 19 professional as possible in that regard. 20 Q. The Ogah -- I want to switch 21 gears, and just, actually, get back to 22 the data. 23 A. I'm starting to feel like 24 Hillary Clinton here. But go ahead.</p>
Page 371	Page 373
<p>1 number to them. These people would come 2 to see me as a patient. 3 And oftentimes I'll say, 4 look, I'd say, how did you come to find 5 me. And they would say, you know, my 6 friend, Kathleen, referred me to you 7 because I have stress incontinence and 8 she says that you're somebody that I 9 would feel comfortable doing my surgery. 10 So in that context, the more 11 that I think about it, a friend of hers, 12 Christine, saw me, and it was a patient 13 that I was going to do her sling for her. 14 My office is on the fourth floor. OR is 15 downstairs. Obviously, I operate at two 16 different hospitals. My recollection is 17 that the friend was closest to that 18 office. 19 So the comment there, 20 clearly, to me, was, you know -- you 21 know, I talked to her about options, and 22 she kept saying, yeah, I want -- I want 23 that procedure that my friend, Kathleen, 24 has mentioned to me. And so she just</p>	<p>1 Q. I want to go back to what 2 you did, reliably assessing the data. 3 The Ogah Cochrane review 4 that was marked, and I'm just referencing 5 Exhibit-5 to Dr. Blaivas's deposition, 6 does that study -- strike that -- does 7 that Cochrane review support your 8 opinions? 9 A. It certainly does. 10 Q. Does that study speak to and 11 document, in a reliable scientific Level 12 1 evidence method, of the lower morbidity 13 and the high safety to the TVT? 14 A. Again, The Cochrane Group, 15 which is an independent group of 16 researchers, physicians, scientists, 17 people with interest in this area, they 18 conduct independent -- it's an 19 international group of individuals. It's 20 not like there's, like, an office that 21 you would go to and this is the Cochrane 22 office. There's -- it's sort of a group 23 of individuals with common interests and 24 they perform very high -- high-level,</p>

Marc Toggia, M.D.

Page 374	Page 376
<p>1 high-quality levels of work. They are 2 widely regarded as one of the reliable 3 sources for this type of Level 1 data. 4 And, exactly, their -- their 5 conclusion is that the minimally invasive 6 synthetic slings, and, again, 7 specifically, they looked at TVT data, 8 does appear to be as effective as the 9 other procedures currently being 10 practiced. 11 Their observation was that 12 there seems to be fewer perioperative 13 complications. And they went on to list 14 specifically which ones, as well. 15 Q. Is there a more recent 16 Cochrane review that assesses the 17 usefulness, utility, efficacy and safety 18 of the TVT? 19 A. I believe earlier this year, 20 led by a gentleman by the name of Ford. 21 In 2015, they updated this, I believe, 22 that -- one of the reasons for this is at 23 the time of the original evaluation, 24 there weren't -- there wasn't a lot of</p>	<p>1 NICE. It stands for the National 2 Institutes of Clinical Excellence. That, 3 actually, I believe, is a government 4 organization in the UK, a group of 5 epidemiologists and other experts that 6 seek to independently evaluate everything 7 from medication to behavioral therapies 8 across the field of medicine, as well as 9 surgical interventions. 10 And those recommendations 11 are typically conveyed to the physicians 12 that are within the UK system. 13 Q. Is that a document that you 14 reviewed and considered in formulating 15 your opinions? 16 A. I did. I mean, I hold that 17 document in the same light as I do the 18 other systematic reviews. 19 Q. I'm going to hand it to you. 20 And I want to mark it for the record. 21 But the -- you said NICE or 22 is it NICE? I'm sorry? 23 A. I'm going to call it NICE. 24 Q. The NICE guidelines says,</p>
Page 375	Page 377
<p>1 good quality data on, say, laparoscopic 2 Burches. You know, again, the thing that 3 was unique about the TVT, it was 4 minimally invasive. 5 They really were hoping to 6 compare it to a more similar minimally 7 invasive. It was felt that the tradition 8 pubovaginal sling, Burch procedures were 9 more invasive. 10 So as they gathered more 11 data, they were able to compare the 12 retropubic TVT to the laparoscopic Burch. 13 At the same time, there was better 14 quality data being generated with regard 15 to transobturator approach and the mini 16 sling as well. 17 So, again, they drew a 18 comparison between the retropubic 19 midurethral sling, specifically TVT, and 20 the other two approaches. 21 Q. You mentioned, I think you 22 said, the NICE guidelines, a little 23 earlier in your testimony? 24 A. NICE, I would pronounce it</p>	<p>1 Use procedures and devices for which 2 there is current high-quality evidence 3 for efficacy and safety. 4 And it's got a Footnote 11. 5 And it says, The guideline only 6 recommends the use of tapes with proven 7 efficacy based on robust RCT evidence. 8 What does that mean? 9 A. That's what I've been 10 speaking to, that, you know -- once you 11 have high-quality, high-level of 12 evidence, you can pretty much draw your 13 conclusions based on that. 14 You know, if there are no 15 Level 1 studies, you know, then you base 16 recommendations on, say, Level 2. I 17 guess for extremely rare interventions, 18 it can go lower than that. 19 But the goal is always to 20 sort of sort out the Level 1 evidence, 21 lower level evidence studies will be 22 looked at mostly to see whether or not 23 they -- they agree or are consistent. 24 But they're usually not used in the</p>

95 (Pages 374 to 377)

Marc Toggia, M.D.

Page 378	Page 380
<p>1 formulation of an -- of an inference.</p> <p>2 Q. And they say, At the time of</p> <p>3 this publication, September 2013, the</p> <p>4 following met the guideline criteria.</p> <p>5 And it lists TVT. I'll just</p> <p>6 hand it to you.</p> <p>7 A. Yes.</p> <p>8 Q. Do you believe that that is</p> <p>9 an accurate statement, based on your own</p> <p>10 independent scientific analysis of the</p> <p>11 data, with regard to the safety of the</p> <p>12 TVT for its intended use to treat stress</p> <p>13 urinary incontinence?</p> <p>14 A. Yes. I mean, I agree with</p> <p>15 the statement that, you know, they only</p> <p>16 recommend the use of tapes that have had</p> <p>17 proven efficacy.</p> <p>18 As, I'm sure, everyone is</p> <p>19 well aware, there are approximately 49</p> <p>20 different mesh products available, some</p> <p>21 have been very well studied, others less</p> <p>22 so, some hardly at all.</p> <p>23 And I think they were -- you</p> <p>24 know, again, they were trying to say, we</p>	<p>1 agreed -- reviewed?</p> <p>2 A. Yes, it is.</p> <p>3 Q. Is that an opinion you</p> <p>4 share?</p> <p>5 A. I share that opinion.</p> <p>6 MR. SNELL: Let's mark that.</p> <p>7 - - -</p> <p>8 (Whereupon, Exhibit</p> <p>9 Toggia-19, NICE Urinary</p> <p>10 Incontinence: The Management of</p> <p>11 Urinary Incontinence in Women, was</p> <p>12 marked for identification.)</p> <p>13 - - -</p> <p>14 BY MR. SNELL:</p> <p>15 Q. Did you see in the</p> <p>16 plaintiffs' experts' depositions where it</p> <p>17 was observed and noted that even one of</p> <p>18 the plaintiffs' experts, when he finally</p> <p>19 decided to discuss TVT in the application</p> <p>20 to treat stress incontinence, Dr. Klinge</p> <p>21 noted, At present, the gold standard in</p> <p>22 SUI surgery is the suburethral sling,</p> <p>23 using either the tension-free vaginal</p> <p>24 tape, TVT, or the transobturator tape.</p>
Page 379	Page 381
<p>1 are -- we are specifically saying that</p> <p>2 our recommendations and our clinical</p> <p>3 recommendations should be to those that</p> <p>4 have robust randomized control trial</p> <p>5 Level 1 data.</p> <p>6 Q. And for the TVT Retropubic</p> <p>7 device, has any other device to treat</p> <p>8 stress incontinence been studied as much,</p> <p>9 as long and as broadly?</p> <p>10 A. No. No. It is the most --</p> <p>11 the retropubic TVT device is the most</p> <p>12 studied anti-incontinence procedure in</p> <p>13 our history.</p> <p>14 I mean, obviously, it's the</p> <p>15 one that I do most commonly. And that is</p> <p>16 certainly based upon, you know, the</p> <p>17 quality of that data.</p> <p>18 Q. That NICE guideline also</p> <p>19 says to use only a Type I macroporous</p> <p>20 mesh?</p> <p>21 A. Yes, it does.</p> <p>22 Q. Is that something you</p> <p>23 believe is a proper statement, based on</p> <p>24 the reliable scientific evidence you</p>	<p>1 Did you see that when you</p> <p>2 reviewed the deposition?</p> <p>3 A. I did -- I did note that Dr.</p> <p>4 Klinge did make that statement.</p> <p>5 Q. And he also referenced Amid</p> <p>6 Type I versus Type III in the Meshia</p> <p>7 study, where there was a 9 percent rate</p> <p>8 of erosion with the intravaginal</p> <p>9 slingplasty, compared to the zero percent</p> <p>10 with the classical TVT which he referred</p> <p>11 to as a Type I macroporous monofilament</p> <p>12 polypropylene mesh.</p> <p>13 Do you recall that?</p> <p>14 A. Yes.</p> <p>15 Q. And you believe that the</p> <p>16 TVT, the retropubic TVT, is the gold</p> <p>17 standard for the treatment of stress</p> <p>18 urinary incontinence?</p> <p>19 A. I think that the -- yes. I</p> <p>20 mean, I think that -- that synthetic</p> <p>21 midurethral slings are currently the most</p> <p>22 commonly practiced anti-incontinence</p> <p>23 procedure.</p> <p>24 I believe that the AGS</p>

Marc Toggia, M.D.

Page 382	Page 384
<p>1 membership, 95 or higher, 99 percent, 2 have done that procedure. I believe 3 within the SUFU, or maybe it's the AUA, 4 which is sort of our colleagues on the 5 urology side, it's in the mid to high 6 80s.</p> <p>7 The procedure is -- is the 8 most common performed worldwide, and 9 seems to have the highest quality of 10 evidence.</p> <p>11 MR. SNELL: Let's mark this 12 as an exhibit, this being the 13 statement by Dr. Klinge 14 acknowledging for the application 15 of stress urinary incontinence 16 treatment, TVT is the gold 17 standard in the macroporous 18 monofilament Amid Type I mesh. 19 - - - 20 (Whereupon, Exhibit 21 Toggia-20, Hernia Repair Surgery, 22 Volker Schumpelick, Robert J. 23 Fitzgibbons, Editors, was marked 24 for identification.)</p>	<p>1 Just if you can confirm, is 2 that the Cochrane review that came out 3 this year that you testified earlier 4 about?</p> <p>5 A. This is the 2015 Cochrane 6 review on midurethral sling operations 7 that was authored by Ford and colleagues.</p> <p>8 Q. And is that a scientifically 9 reliable Level 1 analysis?</p> <p>10 A. The Cochrane review in front 11 of me is thought -- is Level 1 12 meta-analysis, or, in other words, it's a 13 systematic review.</p> <p>14 Q. And in that systematic 15 review, did they look at multiple 16 randomized control trials?</p> <p>17 A. Yes. They would look at 18 Obturator versus Retropubic. They would 19 look at whether you -- devices that were, 20 quote/unquote, bottom to top versus top 21 to bottom. Obturator, left to right, 22 right to left, or, more accurately, in to 23 out, out to in. 24 And I do believe there was</p>
Page 383	Page 385
<p>1 - - - 2 THE WITNESS: If I might be 3 allowed to go off the record to 4 get a glass of water, please?</p> <p>5 MR. SNELL: Sure.</p> <p>6 VIDEO TECHNICIAN: We are 7 off the record. The time is 9:20 8 p.m. 9 - - - 10 (Whereupon, Exhibit 11 Toggia-21, The Cochrane 12 Collaboration; Mid-Urethral Sling 13 Operations for Stress Urinary 14 Incontinence in Women (Review), 15 was marked for identification.) 16 - - - 17 (Whereupon, a discussion off 18 the record occurred.) 19 - - - 20 VIDEO TECHNICIAN: We are 21 back on the video record. 22 BY MR. SNELL: 23 Q. Doctor, I've put before you 24 Exhibit 21.</p>	<p>1 some comparison that looked at types of 2 materials as it relates to cure and time, 3 hospital stay, complications, voiding 4 dysfunctions.</p> <p>5 Q. As you -- strike that.</p> <p>6 As you do your analysis in 7 the body of your report and you comment 8 on the high degree of efficacy that's 9 maintained with the TVT device in the 10 intended treatment of stress 11 incontinence, as well as the low 12 complication rates and the lack of many 13 late complications, even out to 17 years, 14 is that of significance to you in your 15 overall assessment as to whether the TVT 16 is safe for the intended use of treating 17 stress urinary incontinence?</p> <p>18 A. Absolutely.</p> <p>19 Q. Is that data inconsistent 20 with plaintiffs' experts' theories of 21 degradation, cytotoxicity and other claims 22 that there is a high rate of long-term 23 complications? 24 MS. THOMPSON: Object to</p>

97 (Pages 382 to 385)

Marc Toggia, M.D.

Page 386	Page 388
<p>1 form.</p> <p>2 THE WITNESS: It's not</p> <p>3 consistent. I'm not aware, again,</p> <p>4 of any high-quality long-term</p> <p>5 studies that suggest that there is</p> <p>6 a significant -- any significant</p> <p>7 rate -- clinical significant rate</p> <p>8 of long-term complications or</p> <p>9 harm, again, consistently on</p> <p>10 individual bases, perioperative</p> <p>11 risks, roughly in the 2 percent</p> <p>12 range for each individual thing.</p> <p>13 Long-term, you know, what</p> <p>14 I -- what I usually sort of</p> <p>15 summarize to my patients, look,</p> <p>16 over the next ten years, the</p> <p>17 likelihood that you might have to</p> <p>18 have a re-intervention is 3</p> <p>19 and-a-half percent.</p> <p>20 Now, in -- if it's a</p> <p>21 prolapse patient, we say to them,</p> <p>22 look, you know, sometimes there's</p> <p>23 a 15 to 40 percent chance of</p> <p>24 reoperation for prolapse after an</p>	<p>1 trying to highlight the fact that, you</p> <p>2 know, we're not -- we're not -- I wasn't</p> <p>3 asked to do an analysis for nonsurgical</p> <p>4 treatment to surgical treatment. We were</p> <p>5 looking at comparable surgical</p> <p>6 procedures.</p> <p>7 So it's important to say,</p> <p>8 what's the baseline? All these</p> <p>9 procedures operate in the same</p> <p>10 neighborhood, and, roughly speaking, they</p> <p>11 have -- not only do they have similar</p> <p>12 rates of effectiveness, but, overall, the</p> <p>13 rates of complications are elemental.</p> <p>14 They can occur with any of them.</p> <p>15 Bleeding with any surgery,</p> <p>16 obviously; when comparing the different</p> <p>17 techniques, the risks of bleeding are</p> <p>18 somewhat -- are somewhat similar.</p> <p>19 Although, I think the -- the Schimpf --</p> <p>20 excuse me, the Schimpf paper suggested</p> <p>21 that, perhaps, the risk was a little</p> <p>22 lower -- excuse me, the risk was</p> <p>23 significantly lower, say, with a</p> <p>24 midurethral sling compared to a Burch.</p>
Page 387	Page 389
<p>1 initial prolapse procedure.</p> <p>2 These are chronic, you know,</p> <p>3 conditions, as I mentioned several</p> <p>4 times.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. And in your report where you</p> <p>7 analyze the literature and you state, The</p> <p>8 rates of complications requiring surgery</p> <p>9 are consistently less than 5 percent</p> <p>10 across the TVT studies. Overall, the</p> <p>11 data from these high-quality long-term</p> <p>12 studies do not support the claims that</p> <p>13 TVT places a woman at a significant risk</p> <p>14 of long-term chronic complications or the</p> <p>15 need for reoperation as plaintiffs'</p> <p>16 expert suggest.</p> <p>17 A. Yes.</p> <p>18 Q. What did you mean by that?</p> <p>19 A. Were you reading that from</p> <p>20 my report?</p> <p>21 Q. Yes. That was at Page 30.</p> <p>22 I'm sorry, I should have told you where I</p> <p>23 was reading from.</p> <p>24 A. You know, again, I was</p>	<p>1 Bowel and bladder injuries,</p> <p>2 again, these all hovers in that sort of 2</p> <p>3 to 3 percent range.</p> <p>4 You know, longer -- you</p> <p>5 know -- and similar things have been seen</p> <p>6 with other procedures; the needle</p> <p>7 suspension procedures, the autologous</p> <p>8 fascial sling, what we traditionally call</p> <p>9 pubovaginal slings.</p> <p>10 And, again, as I read</p> <p>11 through the literature and tried to come</p> <p>12 up with a number, less than 5 percent</p> <p>13 seemed, to me, to be a very conservative</p> <p>14 number that I would feel comfortable</p> <p>15 discussing with anybody with this</p> <p>16 procedure.</p> <p>17 Q. And did you see, in some of</p> <p>18 the systematic reviews and guidelines,</p> <p>19 where the Retropubic TVT midurethral</p> <p>20 sling had better efficacy or subjective</p> <p>21 improvement than a Burch or a</p> <p>22 pubovaginal, such as Schimpf where they</p> <p>23 saw higher rates of subjective</p> <p>24 improvement so SGS actually recommends</p>

98 (Pages 386 to 389)

Marc Toggia, M.D.

<p style="text-align: right;">Page 390</p> <p>1 midurethral sling over pubovaginal sling?</p> <p>2 A. Yes. And if I can sort of</p> <p>3 qualify that.</p> <p>4 So in my world, we're not</p> <p>5 curing cancer, okay? We are -- we are</p> <p>6 intervening in hopes of improving one's</p> <p>7 quality of life. There are two ways you</p> <p>8 can -- you can assess that result. You</p> <p>9 know, you can simply say to the patient,</p> <p>10 you know, how do you feel? Do you feel</p> <p>11 like you have a substantial improvement?</p> <p>12 Has this resulted in a better quality of</p> <p>13 life? And that's what we would call a</p> <p>14 subjective improvement.</p> <p>15 Stress incontinence is a</p> <p>16 complaint, it's a symptom, it's something</p> <p>17 that someone complains about. That's</p> <p>18 speaks to the subjective nature of</p> <p>19 things.</p> <p>20 It is also a condition that</p> <p>21 can be demonstrated on testing; sometimes</p> <p>22 as simple as saying to a woman, go ahead</p> <p>23 and cough and I see if urine comes out.</p> <p>24 That's done in -- a provocative stress</p>	<p style="text-align: right;">Page 392</p> <p>1 A. Well, the -- I mean, yes.</p> <p>2 Many of them used the same methodologies</p> <p>3 that we use in our own randomized control</p> <p>4 trial.</p> <p>5 MR. SNELL: No more</p> <p>6 questions. Thank you.</p> <p>7 MS. THOMPSON: I have some</p> <p>8 follow-up questions.</p> <p>9 - - -</p> <p>10 EXAMINATION</p> <p>11 - - -</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. First of all, in some of the</p> <p>14 articles that counsel chose to ask you</p> <p>15 about, I'm looking at the Ogah 2011</p> <p>16 Cochrane review.</p> <p>17 And that's one that you</p> <p>18 relied on heavily, correct?</p> <p>19 A. Well, it's one -- yes, it's</p> <p>20 one of the studies that's -- that was</p> <p>21 part of the very large pile of Level 1</p> <p>22 studies.</p> <p>23 Q. And I think we're both</p> <p>24 looking at the Neurourology and</p>
<p style="text-align: right;">Page 391</p> <p>1 test is done in a variety of situations,</p> <p>2 sometimes with formal testing, oftentimes</p> <p>3 without formal testing.</p> <p>4 Or you might put a pad on a</p> <p>5 woman and say, okay, you know, give me</p> <p>6 100 jumping jacks. That's objective.</p> <p>7 So they do tend to look at</p> <p>8 both subjective and objective. We argue</p> <p>9 back and forth with each other, what's</p> <p>10 more important. Again, being practically</p> <p>11 minded, oftentimes we'll say, you know,</p> <p>12 the patient is happy subjectively, we</p> <p>13 would give quite a bit of weight to that.</p> <p>14 So we do break them out separately.</p> <p>15 Sometimes they'll come up with a</p> <p>16 composite score.</p> <p>17 So, fortunately, these</p> <p>18 trials were well designed and approached</p> <p>19 the -- they objectively approached both</p> <p>20 subjective measures and objective</p> <p>21 measures in both groups.</p> <p>22 Q. And you found -- did you</p> <p>23 find those data reliable in order to</p> <p>24 be --</p>	<p style="text-align: right;">Page 393</p> <p>1 Urodynamics summary of the Cochrane</p> <p>2 study, correct?</p> <p>3 A. Yes. Given this is not 900</p> <p>4 pages, I'm going to say this is the</p> <p>5 summary.</p> <p>6 Q. Right. Could you turn to</p> <p>7 Page 289? And I'm going to read the</p> <p>8 paragraph under quality of evidence.</p> <p>9 The quality of evidence for</p> <p>10 the majority of trials was moderate, with</p> <p>11 a minority having low to moderate levels</p> <p>12 of evidence. However, the total number</p> <p>13 of trials, 61, including 7,021 women was</p> <p>14 high and it was possible to explore the</p> <p>15 effects of different routes of insertion</p> <p>16 of the tapes and different tape</p> <p>17 materials.</p> <p>18 On the other hand, very few</p> <p>19 trials reported outcomes after one year</p> <p>20 and the long-term efficacy and adverse</p> <p>21 events have yet to be determined.</p> <p>22 Would you agree that, at</p> <p>23 least according to the Cochrane review of</p> <p>24 19 -- of 2011, adverse events were yet to</p>

99 (Pages 390 to 393)

Marc Toggia, M.D.

Page 394	Page 396
<p>1 be determined?</p> <p>2 MR. SNELL: Objection.</p> <p>3 Misstates the document.</p> <p>4 BY MS. THOMPSON:</p> <p>5 Q. Did I not read that</p> <p>6 correctly, the document?</p> <p>7 A. Um --</p> <p>8 Q. No. First of all -- first</p> <p>9 of all, did I read that paragraph</p> <p>10 correctly?</p> <p>11 A. You read the paragraph</p> <p>12 correctly.</p> <p>13 And I just want -- in</p> <p>14 forming my answer, we're talking</p> <p>15 specifically about comparative trials.</p> <p>16 We're not talking about long-term trials,</p> <p>17 we're talking about, specifically, trials</p> <p>18 that randomized women to one approach,</p> <p>19 Retropubic, versus a different approach,</p> <p>20 Obturator, and the duration that the</p> <p>21 trial went on for.</p> <p>22 This is -- this is an</p> <p>23 internal comparison between different</p> <p>24 types of midurethral slings.</p>	<p>1 A. Yes.</p> <p>2 Q. -- but Ogah determined that</p> <p>3 the adverse events have yet to be</p> <p>4 determined.</p> <p>5 Reading further in that --</p> <p>6 in the section that says, Conclusions,</p> <p>7 implications for practice, the last</p> <p>8 paragraph states, However, there is</p> <p>9 little evidence about the long-term</p> <p>10 effectiveness or the chance of adverse</p> <p>11 events, such as tape erosions nor is it</p> <p>12 clear how to treat women after a tape</p> <p>13 procedure fails.</p> <p>14 You would agree with me that</p> <p>15 that was a conclusion that Ogah made in</p> <p>16 the 2011 Cochrane review? I'm just</p> <p>17 reading it.</p> <p>18 A. That's fine. Point to it</p> <p>19 again.</p> <p>20 Q. The last paragraph under,</p> <p>21 Conclusions, implications for practice.</p> <p>22 A. Right. The last sentence</p> <p>23 speaks to, you know, should you undergo a</p> <p>24 midurethral sling, that these particular</p>
Page 395	Page 397
<p>1 Q. But the report does say that</p> <p>2 very few trials reported outcomes after</p> <p>3 one year and the long-term efficacy and</p> <p>4 adverse events have yet to be determined,</p> <p>5 correct?</p> <p>6 A. Very few studies that have</p> <p>7 compared one method to the other.</p> <p>8 Q. Okay. That's what the</p> <p>9 article states, what I just read,</p> <p>10 correct?</p> <p>11 MR. SNELL: Objection.</p> <p>12 Asked and answered.</p> <p>13 MS. THOMPSON: No. It's a</p> <p>14 simple question.</p> <p>15 THE WITNESS: Again, the</p> <p>16 comparative analysis was limited</p> <p>17 to Retropubic, bottom to top</p> <p>18 versus top to bottom; Obturator,</p> <p>19 medial to lateral versus lateral</p> <p>20 to medial; monofilament versus</p> <p>21 multifilament; Transobturator</p> <p>22 versus Retropubic.</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. That's all true --</p>	<p>1 studies analyze -- do not answer the</p> <p>2 question of what you would do subsequent.</p> <p>3 Q. But I did read that</p> <p>4 paragraph correctly as a conclusion of</p> <p>5 Ogah in this study?</p> <p>6 A. You did.</p> <p>7 Q. And then in the next</p> <p>8 section, Implications for research.</p> <p>9 There is a need to address some of the</p> <p>10 limitations of a number of the trials</p> <p>11 contributed -- contributing to the</p> <p>12 synthesis, particularly in improving the</p> <p>13 methodology of the trials or their</p> <p>14 reporting. It is highly recommended that</p> <p>15 clinical trials should be reported</p> <p>16 following the CONSORT guidelines.</p> <p>17 Did I read that paragraph</p> <p>18 correctly?</p> <p>19 A. Yes.</p> <p>20 Q. So Ogah, at least, states</p> <p>21 that there is -- that there are</p> <p>22 limitations to a number of these trials,</p> <p>23 and that -- particularly, improving the</p> <p>24 methodology of the trials and the</p>

100 (Pages 394 to 397)

Marc Toggia, M.D.

Page 398	Page 400
<p>1 reporting, correct?</p> <p>2 MR. SNELL: Objection.</p> <p>3 Form.</p> <p>4 THE WITNESS: That's their</p> <p>5 recommendations. That their --</p> <p>6 they would like to see additional</p> <p>7 trials that would conform to the</p> <p>8 criteria that they use.</p> <p>9 And, again, their primary</p> <p>10 objective is that they want to</p> <p>11 compare apples with apples.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. And the next paragraph, in</p> <p>14 implications for research, There is a</p> <p>15 need for more robustly designed, good</p> <p>16 quality and adequately powered randomized</p> <p>17 controlled trials with standardized</p> <p>18 objectives and validated subjective</p> <p>19 outcomes. These trials need to have</p> <p>20 long-term follow-up and adequate</p> <p>21 reporting of adverse events.</p> <p>22 Is that one of the</p> <p>23 implications for research that Ogah lists</p> <p>24 in the 2011 Cochrane review that you're</p>	<p>1 quality --</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. Of a new complication, never</p> <p>4 reported before?</p> <p>5 A. Case series in general.</p> <p>6 Q. I'm talking about case</p> <p>7 series of a new complication that has not</p> <p>8 previously been reported?</p> <p>9 MR. SNELL: Objection.</p> <p>10 THE WITNESS: Sure.</p> <p>11 MR. SNELL: He's already</p> <p>12 answered this and said no.</p> <p>13 MS. THOMPSON: He said he</p> <p>14 misunderstood my question. He</p> <p>15 thought he -- I was talking about</p> <p>16 case specific -- case series in</p> <p>17 general, and I'm talking about</p> <p>18 case series reporting a new</p> <p>19 complication.</p> <p>20 THE WITNESS: I'm sorry.</p> <p>21 MS. THOMPSON: Those are two</p> <p>22 different things.</p> <p>23 THE WITNESS: I'm talking</p> <p>24 about all case series, which would</p>
Page 399	Page 401
<p>1 relying on?</p> <p>2 A. It's a suggestion.</p> <p>3 Q. You'll agree with me that</p> <p>4 case series can be quite significant if</p> <p>5 they're reporting a new complication,</p> <p>6 correct?</p> <p>7 MR. SNELL: Objection.</p> <p>8 THE WITNESS: I would not</p> <p>9 agree with that, counselor, no.</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. So a new complication never</p> <p>12 reported about, that's published in a</p> <p>13 case series, you'll agree that those are</p> <p>14 seen frequently in prestigious journals</p> <p>15 and considered to be important?</p> <p>16 MR. SNELL: Objection.</p> <p>17 Foundation. Compound.</p> <p>18 THE WITNESS: I mean, I</p> <p>19 think -- I can tell you that in</p> <p>20 the journals that I work for, they</p> <p>21 are no longer interested in</p> <p>22 publishing those with any great</p> <p>23 frequency because they don't</p> <p>24 consider them to be high</p>	<p>1 include the type of case series</p> <p>2 that you're referring to.</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Okay. And just</p> <p>5 specifically, case series reporting a new</p> <p>6 complication are deemed important</p> <p>7 frequently, correct?</p> <p>8 MR. SNELL: Objection.</p> <p>9 Asked and answered.</p> <p>10 THE WITNESS: Are deemed</p> <p>11 important frequently?</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. Are frequently deemed</p> <p>14 important in journals?</p> <p>15 MR. SNELL: Same objection.</p> <p>16 Asked and answered.</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. If you disagree with it,</p> <p>19 just say you disagree with it.</p> <p>20 A. I disagree.</p> <p>21 I mean, just, again, I -- I</p> <p>22 serve on the editorial board and those</p> <p>23 are not manuscripts that we frequently</p> <p>24 review.</p>

101 (Pages 398 to 401)

Marc Toggia, M.D.

Page 402	Page 404
<p>1 Q. Okay. Let's look at</p> <p>2 Schimpf, another one of the articles that</p> <p>3 counsel chose to ask you about and that</p> <p>4 you relied on for your opinions, correct?</p> <p>5 A. That is correct.</p> <p>6 Q. Let's go to the -- to Page</p> <p>7 71.E18.</p> <p>8 A. I'm sorry, obviously, I'm</p> <p>9 not able to predict what you're going to</p> <p>10 ask me next, so I don't have it.</p> <p>11 Q. I'm going to ask you about</p> <p>12 the articles that --</p> <p>13 A. No, I'm just asking for</p> <p>14 permission to go off record so I find</p> <p>15 that article.</p> <p>16 Q. It shouldn't take you that</p> <p>17 long.</p> <p>18 A. No, I don't -- I'm just</p> <p>19 trying to be respectful of everybody's</p> <p>20 time on a Friday evening.</p> <p>21 Q. Do you have Schimpf in front</p> <p>22 of you?</p> <p>23 A. I do.</p> <p>24 Q. Okay. If you could turn to</p>	<p>1 about postoperative symptoms, such as</p> <p>2 urgency and de novo urgency, these</p> <p>3 symptoms were inconsistently reported,</p> <p>4 thus limiting their analysis.</p> <p>5 Additionally, data</p> <p>6 concerning need for re-treatment were</p> <p>7 sparse and inconsistent, limiting our</p> <p>8 ability to draw any conclusions on this</p> <p>9 important question. Complications were</p> <p>10 assessed at different time intervals</p> <p>11 among different trials, and sometimes</p> <p>12 later trials reporting secondary analysis</p> <p>13 did not update longer-term AEs. The vast</p> <p>14 majority did not use a standard</p> <p>15 classification for complications, such as</p> <p>16 the classification system of Dindo, et</p> <p>17 al.</p> <p>18 Did I read that correctly</p> <p>19 about Schimpf's conclusions regarding the</p> <p>20 reporting of AEs?</p> <p>21 MR. SNELL: Objection.</p> <p>22 Misstates.</p> <p>23 Go ahead.</p> <p>24 MS. THOMPSON: I just asked</p>
Page 403	Page 405
<p>1 Page 71.E18?</p> <p>2 A. Counselor, I'm not sure that</p> <p>3 we're back on record.</p> <p>4 Q. We never went off the</p> <p>5 record.</p> <p>6 A. My apologies.</p> <p>7 Q. And I'm reading --</p> <p>8 A. I was waiting to hear that.</p> <p>9 So I did not focus on your question.</p> <p>10 Could you repeat that, please?</p> <p>11 Q. 71.E18. And I'm reading</p> <p>12 from the paragraph that begins there,</p> <p>13 Limitations to the study.</p> <p>14 And Schimpf states here,</p> <p>15 There was also high variability in</p> <p>16 reporting of numbers and types of</p> <p>17 complications in trials, making analysis</p> <p>18 of AE outcomes challenging.</p> <p>19 And AE stands for adverse</p> <p>20 events, correct?</p> <p>21 A. I would agree that</p> <p>22 adverse -- AE stands for adverse events.</p> <p>23 Q. While many surgeons and</p> <p>24 patients are interested in information</p>	<p>1 if I read it correctly.</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. Did I read it correctly,</p> <p>4 Doctor?</p> <p>5 A. You did, counselor.</p> <p>6 MR. SNELL: You said</p> <p>7 conclusion. So I'm going to</p> <p>8 object. That's my objection.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. Are you familiar with the</p> <p>11 Brubaker paper that was published</p> <p>12 recently that was critical of two of the</p> <p>13 randomized surgical trails for urinary</p> <p>14 incontinence?</p> <p>15 MR. SNELL: Form. Vague.</p> <p>16 THE WITNESS: Dr. Brubaker</p> <p>17 is so prolific, I don't know which</p> <p>18 one you're talking about.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. The title is, Missing Data</p> <p>21 Frequency and Correlates in Two</p> <p>22 Randomized Surgical Trials for Urinary</p> <p>23 Incontinence in Women.</p> <p>24 A. I'm not familiar with that,</p>

102 (Pages 402 to 405)

Marc Toggia, M.D.

Page 406	Page 408
<p>1 no.</p> <p>2 Q. So you -- and it's in the</p> <p>3 IUJ, do you read that journal that you're</p> <p>4 the editor of?</p> <p>5 A. I read that journal. I</p> <p>6 can't tell you I read everything that's</p> <p>7 published within that journal.</p> <p>8 Q. Would that have been</p> <p>9 something interesting to you, to</p> <p>10 determine that two randomized surgical</p> <p>11 trials had missing visits and data</p> <p>12 increasing with time?</p> <p>13 MR. SNELL: Objection.</p> <p>14 Calls for speculation.</p> <p>15 THE WITNESS: All -- all</p> <p>16 clinical trials suffer from that</p> <p>17 occurrence.</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. At least somebody at the IUJ</p> <p>20 thought that was significant enough to be</p> <p>21 published, correct?</p> <p>22 MR. SNELL: You're asking</p> <p>23 him to comment on something that</p> <p>24 he doesn't recall seeing? If</p>	<p>1 see if there are benign inflammatory</p> <p>2 tumors associated with TVT?</p> <p>3 MR. SNELL: Objection.</p> <p>4 Relevance.</p> <p>5 THE WITNESS: In the</p> <p>6 research that I did in formulating</p> <p>7 my opinion, I did not come across</p> <p>8 such an article.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. What is your definition of a</p> <p>11 medical device?</p> <p>12 A. A medical device, I would</p> <p>13 consider to be -- I think in the United</p> <p>14 States devices need to be approved by the</p> <p>15 FDA and the -- excuse me, the specific</p> <p>16 indication for that device needs to be</p> <p>17 stated.</p> <p>18 Q. You've used the word</p> <p>19 "approved" several times today.</p> <p>20 Do you mean cleared?</p> <p>21 A. I suspect that I mean</p> <p>22 cleared. To me, approved, cleared.</p> <p>23 Q. And so you're not claiming</p> <p>24 to be a regulatory expert, correct?</p>
Page 407	Page 409
<p>1 you've got it --</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. You can answer.</p> <p>4 MR. SNELL: If you've got</p> <p>5 it, print it out and put it on the</p> <p>6 record. I don't care. But don't</p> <p>7 ask him to speculate.</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. You can -- you can answer</p> <p>10 the question.</p> <p>11 A. It was published, so an</p> <p>12 editor felt that it was worthy of</p> <p>13 publication.</p> <p>14 Q. Are you aware of</p> <p>15 publications reporting inflammatory</p> <p>16 tumors associated with the TVT?</p> <p>17 MR. SNELL: Objection.</p> <p>18 Form. Foundation. Associated.</p> <p>19 THE WITNESS: I'm sorry, I'm</p> <p>20 not familiar -- I'm not aware of a</p> <p>21 publication that makes -- makes</p> <p>22 that claim, no.</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Have you ever researched to</p>	<p>1 A. I'm familiar with the</p> <p>2 regulatory process, probably more so than</p> <p>3 the average citizen.</p> <p>4 Q. And, yet, you don't know the</p> <p>5 difference between cleared and approved?</p> <p>6 A. I'm saying that I use both</p> <p>7 terms interchangeably.</p> <p>8 Q. So those two terms are</p> <p>9 interchangeable in your mind?</p> <p>10 A. I mean, approved, to me,</p> <p>11 means it's approved for use.</p> <p>12 Q. Is the answer yes?</p> <p>13 A. I consider them in the</p> <p>14 same -- in the same light.</p> <p>15 Q. I'm going to read you the</p> <p>16 World Health Organization definition of</p> <p>17 medical device and ask you if you would</p> <p>18 agree with that definition, okay?</p> <p>19 A. Okay.</p> <p>20 Q. Medical device means any</p> <p>21 instrument, apparatus, implement,</p> <p>22 machine, appliance, implant, reagent for</p> <p>23 in vitro use, software, material or other</p> <p>24 similar or related article intended by</p>

103 (Pages 406 to 409)

Marc Toggia, M.D.

Page 410	Page 412
<p>1 the manufacturer to be used alone or in 2 combination for human beings for one or 3 more of the specific medical purposes 4 of...</p> <p>5 Does that sound like a 6 definition of medical device -- device 7 that you would agree with?</p> <p>8 MR. SNELL: Objection. 9 Foundation.</p> <p>10 THE WITNESS: I'll take what 11 you say at face value, counselor. 12 That sounds like a reasonable 13 definition.</p> <p>14 BY MS. THOMPSON: 15 Q. Were PROLENE® sutures 16 cleared by the FDA? 17 A. I don't believe that 18 PROLENE® sutures, per se, are considered 19 a medical device. 20 Q. That wasn't my question. 21 My question was, were 22 PROLENE® sutures cleared by the FDA as a 23 medical device? 24 A. I thought that's what I just</p>	<p>1 medical device that I -- definition that 2 I just read to you from the World Health 3 Organization?</p> <p>4 MR. SNELL: Form. 5 THE WITNESS: I don't -- I'd 6 have to see it again, sort of -- 7 in writing, counselor. That a 8 rather complicated -- 9 BY MS. THOMPSON: 10 Q. Is it a material? 11 A. A suture is a material. 12 Q. Does a suture usually come 13 with a needle attached? 14 A. It may or may not have a 15 needle attached. 16 Q. If it does have a needle 17 attached, is that an apparatus? 18 A. I would assume that it could 19 be considered an apparatus. 20 Q. Is it used for human beings? 21 A. Yes. 22 Q. Is it used for a medical 23 purpose? 24 A. Yes.</p>
Page 411	Page 413
<p>1 said. I mean, I don't know. I'm not 2 aware that they are, A, categorized by a 3 medical device. If they were categorized 4 by a medical device, I would assume they 5 were cleared. But I don't know what 6 category sutures fall into.</p> <p>7 Q. I'll represent to you that 8 sutures -- PROLENE® suture was cleared by 9 the FDA as a --</p> <p>10 MR. SNELL: That is a total 11 misrepresentation. 12 BY MS. THOMPSON: 13 Q. -- approved by the FDA as a 14 medical device.</p> <p>15 MR. SNELL: It was approved 16 as a drug by the FDA, found to be 17 safe and effective. You know 18 that's a blunt misrepresentation 19 to the witness. And then 20 re-categorized as a device. 21 MS. THOMPSON: Forgive me. 22 It was re-categorized as a device. 23 BY MS. THOMPSON: 24 Q. Would a suture fit the</p>	<p>1 Q. Wouldn't you agree that that 2 fits the definition of the World Health 3 Organization of a medical device? 4 MR. SNELL: Objection to 5 form. 6 THE WITNESS: The way that 7 you described it to me, I would 8 take your word that that's how it 9 is classified.</p> <p>10 BY MS. THOMPSON: 11 Q. Okay. Thank you. 12 Did I hear you correctly 13 that you track your complications in your 14 practice using mental notes? 15 MR. SNELL: Misstates. 16 Go ahead. 17 THE WITNESS: We track our 18 complications on -- on 19 spreadsheets, on paper. 20 BY MS. THOMPSON: 21 Q. And we could request those 22 spreadsheets and papers that track your 23 complications? 24 A. I don't know that those</p>

104 (Pages 410 to 413)

Marc Toggia, M.D.

Page 414	Page 416
<p>1 exist beyond a certain period of time. 2 They're not published. 3 Q. And you don't have those in 4 your office that we can look at? 5 A. I'm sorry, I do not. 6 MS. THOMPSON: I have -- 7 BY MS. THOMPSON: 8 Q. Oh, I have another question. 9 If I were to show you 10 internal Ethicon documents that show 11 degradation, show surface cracking, show 12 the clinical significance and show the 13 histological diagnosis of degradation, 14 would you still hold on to your opinion 15 that polypropylene does not degrade? 16 MR. SNELL: Objection. 17 Foundation. Form. 18 THE WITNESS: I would. 19 Because, again, the Level 1 20 evidence on safety would trump 21 lower levels of evidence, which 22 would include in vitro studies 23 that you're referring to or even 24 animal studies.</p>	<p>1 CERTIFICATE 2 3 4 I HEREBY CERTIFY that the 5 witness was duly sworn by me and that the 6 deposition is a true record of the 7 testimony given by the witness. 8 9 10 11 Amanda Maslynsky-Miller 12 Certified Realtime Reporter 13 Dated: October 5, 2015 14 15 16 17 (The foregoing certification 18 of this transcript does not apply to any 19 reproduction of the same by any means, 20 unless under the direct control and/or 21 supervision of the certifying reporter.) 22 23 24</p>
Page 415	Page 417
<p>1 MS. THOMPSON: No further 2 questions. 3 MR. SNELL: No questions. 4 VIDEO TECHNICIAN: This 5 concludes the deposition. We are 6 off the record. The time is 9:50 7 p.m. 8 - - - 9 (Whereupon, the deposition 10 concluded at 9:50 p.m.) 11 - - - 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason 6 in the appropriate space on the errata 7 sheet for any corrections that are made. 8 After doing so, please sign 9 the errata sheet and date it. 10 You are signing same subject 11 to the changes you have noted on the 12 errata sheet, which will be attached to 13 your deposition. 14 It is imperative that you 15 return the original errata sheet to the 16 deposing attorney within thirty (30) days 17 of receipt of the deposition transcript 18 by you. If you fail to do so, the 19 deposition transcript may be deemed to be 20 accurate and may be used in court. 21 22 23 24</p>

105 (Pages 414 to 417)

Marc Toglia, M.D.

Page 418	Page 420
<div style="text-align: center; margin-bottom: 10px;"> ----- ERRATA ----- </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">1</div> <div style="width: 80%;">PAGE LINE CHANGE/REASON</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">2</div> <div style="width: 80%;"></div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">3</div> <div style="width: 80%;"></div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">4</div> <div style="width: 80%;"></div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">5</div> <div style="width: 80%;"></div> <div style="width: 10%;"></div> </div> <div style="display: flex; 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<div style="text-align: right; padding-bottom: 10px;">Page 419</div> <div style="text-align: center; margin-bottom: 10px;"> ACKNOWLEDGMENT OF DEPONENT </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">1</div> <div style="width: 80%;">I, _____, do</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">2</div> <div style="width: 80%;"></div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">3</div> <div style="width: 80%;">hereby certify that I have read the</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">4</div> <div style="width: 80%;">foregoing pages, 1 - 415, and that the</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">5</div> <div style="width: 80%;">same is a correct transcription of the</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">6</div> <div style="width: 80%;">answers given by me to the questions</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">7</div> <div style="width: 80%;">therein propounded, except for the</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">8</div> <div style="width: 80%;">corrections or changes in form or</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">9</div> <div style="width: 80%;">substance, if any, noted in the attached</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 10%; text-align: right;">10</div> <div style="width: 80%;">Errata Sheet.</div> <div style="width: 10%;"></div> </div> <div style="display: flex; justify-content: space-between;"> </div>	

106 (Pages 418 to 420)

Marc Toggia, M.D.

Page 421

A	accuracy 330:3	35:11,12	advice 166:2	158:20 159:5
abbott 163:3	accurate 69:18	197:20,22	313:19	160:1 186:23
168:1 169:13	183:14 211:7	309:19 323:23	advocate 287:3	190:10 201:9
169:16 173:12	221:12,16	additional 29:23	ae 403:18,19,22	204:9,10
173:22,24	265:15,15	35:17 37:9	aes 404:13,20	214:19 229:16
174:13 358:17	277:19 280:10	39:3,17,20	affair 319:4	248:23 255:18
358:22	291:5 306:19	40:3 129:12	affect 104:18	285:3 343:18
ability 35:16	324:18 339:15	191:6 275:3	316:21	351:23 355:14
404:8	378:9 417:20	362:7 398:6	affiliated 316:18	372:24 390:22
able 67:19 68:4	accurately	additionally	ages 17:21 18:13	404:23 413:16
80:8 111:22	227:4 280:6	174:2 177:7	aggregate	airplane 293:13
170:13,16	384:22	192:14 404:5	265:11	al 1:8,8,9,9,10
201:2 236:19	achieved 322:24	additions 27:1	ago 209:22	1:11,11,12,12
330:2 336:23	acid 239:23	additives 144:17	297:16 310:17	1:13,13,14,15
375:11 402:9	240:2 348:15	144:21 145:4	agree 15:2 19:3	1:15,16,17,17
absolutely 43:6	acids 348:9	address 11:7	40:15,19	1:18 2:2,3,3,4
104:1 131:7	acknowledge	46:14 105:24	122:17,20	2:4,5,5,6,6,7,7
150:6 195:15	46:8 173:13	151:13 237:9	125:23 126:21	2:8,8,9,10,11
195:17 208:16	199:22 348:21	320:11 346:8	127:6 190:4	2:12,13,14,15
250:4 263:14	350:9,13	397:9	202:18 211:23	2:15,16,16,17
271:11 327:11	acknowledged	addressed 361:7	212:23 213:21	2:18,18,19,19
335:7 341:17	352:3	361:10 362:13	214:7,15	2:20,21,22,22
342:11 385:18	acknowledging	addresses 343:6	219:20 221:3	3:2,2,3,4,4,5,5
absorbed 291:1	382:14	addressing	223:7 226:13	3:6,6 333:5
abstract 175:24	acknowledgm...	106:2	226:13 257:21	340:14 404:17
176:22	419:1	adequacy 339:7	258:3 262:1	albeit 352:9
abstracted	act 317:14	adequate 272:20	285:8 377:23	albo 121:8
176:23	acting 271:14	273:7 398:20	378:14 393:22	algorithm
abundant	action 291:3	adequately	396:14 399:3,9	217:11
171:19	actions 290:16	398:16	399:13 403:21	allotted 201:4
academic 11:15	active 304:22	adhere 251:6	409:18 410:7	allow 16:13
12:4,8,12,16	activities 312:11	adjacent 290:24	413:1	39:10 192:7
316:17	activity 80:6	admit 313:23	agreed 9:3 380:1	287:19 358:19
academician	actual 116:3	ads 264:13	agreement 6:20	allowed 24:14
358:12	216:13 306:7	advantage	296:10 302:21	154:3 270:17
accept 186:20	acute 207:1	329:12,20	302:24 303:13	383:3
284:19 299:15	ad 309:8 310:4	adverse 272:5	303:17,22	allows 258:15,17
acceptable	adaptation	289:3 353:23	agreements	284:11,21
231:9,19	284:11,21	354:6 356:21	302:19	285:9,14
260:22	285:10	359:21 393:20	ags 381:24	316:13
accepted 78:1	adaptations	393:24 395:4	ahead 14:8	alter 143:9
79:24	285:14	396:3,10	18:16 35:6,16	altered 350:11
accepting 316:5	add 323:15	398:21 403:19	39:16 43:4	alternative
316:19	added 144:21	403:22,22	44:6 90:15,17	92:22 224:15
access 31:6	145:15,16	advertise 308:24	98:11 100:8	360:7,9
165:7	adding 145:8	advertisement	103:17 147:13	alternatives
	addition 34:3,18	309:22	154:11,23	211:24

Marc Toggia, M.D.

Page 422

amanda 3:18 9:24 98:10 416:10 ambulatory 17:5 american 335:13 amid 55:9 259:15 381:5 382:18 amino 348:9,15 amount 62:4 78:2 80:6 145:1 153:9,11 200:20 216:14 252:16 263:23 323:10 anal 75:8,10 analogous 267:12 analyses 328:11 334:19 analysis 40:23 53:18 54:7,7 333:19 334:23 343:6,11 344:24 347:6 347:17 349:3 363:5 378:10 384:9 385:6 388:3 395:16 403:17 404:4 404:12 analytical 349:7 analyze 342:2 350:14 387:7 397:1 analyzed 343:20 347:4 350:7 analyzing 342:3 342:7 anaphylaxis 189:7 andahalf 85:10 130:9 386:19 anesthesia 286:10,12,18	286:18,19,23 287:1,4,5,7,13 287:23 288:6 anesthesiologist 286:24 angiogenesis 258:19 animal 38:21 146:20 243:6,8 290:17 324:4 324:13 369:10 414:24 annual 14:2 181:23 annually 156:15 166:3,11 answer 8:5 17:23 18:1,16 18:18,20 46:16 50:9 53:23 55:23 56:19 97:19 98:2,5,8 98:12,19,21,23 107:12 113:6 118:16 153:18 154:11,22 158:15 159:5 160:13,21 161:5 163:20 164:1,5,13,22 166:20 167:5 171:9 176:24 177:2 181:22 192:8 193:21 194:1 196:12 197:4,6,12 203:23 204:10 231:4 232:9 234:7 235:17 235:20 236:1 236:22 241:18 248:15 252:21 260:22 268:21 270:8 274:19 274:20 280:24 285:22 355:6 394:14 397:1	407:3,9 409:12 answered 41:5 47:24 50:7,14 50:16 97:24 99:10,16 102:20 125:2 139:4 149:10 163:22 164:3 167:3 171:8 177:20 203:16 203:21 235:15 395:12 400:12 401:9,16 answering 170:3 171:11 answers 160:19 161:11,13 419:4 anterior 74:11 antiincontine... 64:24 127:9 185:10 224:8 275:1 276:7 331:22 365:23 379:12 381:22 anybody 55:19 56:6 146:1 389:15 apical 265:1 266:22 apogee 104:22 apologies 175:9 311:18 403:6 apologize 120:23 157:4 221:24 283:21 331:1 apologizing 200:20 apparatus 409:21 412:17 412:19 apparent 224:23 apparently 90:3 appear 374:8 appearance 352:9	appearances 4:1 appears 100:6 apples 78:6,6 398:11,11 appliance 409:22 applicable 134:12 194:20 application 255:1 324:9 325:8 367:18 369:15 380:19 382:14 applications 368:5 applied 252:17 368:4 applies 110:15 apply 139:7 255:3 416:18 appointment 11:16 12:5 157:24 appointments 12:13,17 appreciate 19:3 25:1 92:6 96:2 207:7 222:12 apprised 30:20 approach 334:24 335:1 375:15 394:18 394:19 approached 391:18,19 approaches 333:21 375:20 appropriate 18:11 65:1 87:12 93:23 107:5 167:21 214:10 231:13 232:12 235:8 237:4 356:5 357:10 417:6 approved 5:21 79:16,17 80:2	80:22 81:1 87:20 408:14 408:19,22 409:5,10,11 411:13,15 approximate 27:24 66:5 approximately 28:10,11,14,15 67:16 70:5 120:5 332:21 378:19 april 109:3 area 55:18 56:3 76:17 146:8 186:4 215:20 241:13 259:5 365:22 373:17 areas 19:21 53:10,13 272:3 272:4 argue 128:8 391:8 argument 183:21 argumentative 90:14 92:15 95:12,16,20 96:7 97:10 235:23 319:14 arm 345:8 arrangement 306:3 article 168:5 195:18 222:20 222:23 223:11 223:15 231:11 305:14 351:16 395:9 402:15 408:8 409:24 articles 29:3 31:20 32:5,10 32:19,20 211:6 223:2 316:15 327:22 368:1 392:14 402:2 402:12
---	---	--	--	---

Marc Toggia, M.D.

Page 423

articulating 111:6	132:1,24 133:3 139:8 148:22	atlanta 209:21	average 144:12 182:3 215:11	172:16 173:24 194:17 199:18
asian 223:23	151:1 160:21	attached 21:24 23:20 26:20	409:3	200:12 204:7
asked 22:3 41:5 47:23 50:14,23 60:4 66:22 69:2,6,7 73:6 94:20 95:4,7 97:19,23 98:9 102:19 104:4,8 125:2 139:4,11 144:4 148:24 149:10 157:22 158:14 160:4,8 160:9 161:15 164:3 167:3 168:24 169:1 171:7,14 172:5 176:20 177:20 177:21 192:5 193:2,9,19 196:20,21 197:2,8 203:20 211:9 225:10 232:6 235:14 250:8 280:22 286:5 292:7 308:1 318:17 320:15 330:14 331:4 335:8,19 339:14,23 342:2 345:13 345:24 347:22 347:23 353:2,6 354:23 358:18 359:23 360:11 361:3 363:17 367:5 369:22 372:15 388:3 395:12 401:9 401:16 404:24	161:1,20 167:6 182:14 183:4 197:8 233:11 233:16,18 236:7,15 246:20 250:9 311:2 320:18 402:13 406:22 asks 24:13 44:21 asleep 287:6 assess 325:20 334:1 341:4 346:19 360:17 390:8 assessed 332:16 404:10 assesses 374:16 assessing 322:16 327:7 339:6,10 368:11 373:2 assessment 331:12 333:4 385:15 assistance 219:5 associate 11:18 11:22,23 associated 44:13 46:5 49:1 113:1 114:6 126:6 407:16 407:18 408:2 association 335:14 assume 87:4 274:14 285:13 289:13 306:20 411:4 412:18 assuming 87:5 294:13 assumption 102:1 asymptomatic 189:23 atkins 1:17	atlanta 209:21 attached 21:24 23:20 26:20 31:13 34:8 267:7 299:4 412:13,15,17 417:12 419:6 attachment 230:1 attempt 80:11 attend 60:16 70:16 318:18 attending 62:16 attention 239:14 attorney 30:16 48:6 417:16 atypical 163:8 aua 198:5 328:17 382:3 aug 41:19 42:8 42:9,17 45:4 45:21 48:17,21 198:6 317:10 330:14 331:5 331:11 332:22 333:23 335:3 august 30:8 austria 170:12 171:1,24 author 192:18 authored 384:7 authors 43:12 43:16 348:17 352:3,7 358:23 autologous 115:6 184:20 212:16 214:9 215:16 217:2,4 217:7,13,14 218:10 219:2 266:3,19 267:4 267:6,18 340:11 359:24 360:6 389:7 available 66:21 76:13 78:5 113:12 378:20	avoid 105:6 106:18,21 274:15 awards 315:17 aware 60:10 71:11,22 107:4 132:5,8,15,20 132:22 133:6 133:19 135:8 138:14,23 139:23 142:21 143:23 146:19 162:12,19 190:15 196:6 196:21,23 204:15,22 205:5,6 209:4 209:8 223:17 234:13 241:19 252:22 255:21 256:21 269:10 273:20 281:4,8 281:10 288:14 292:21 300:3 308:14,17 312:12 315:23 317:13 345:21 378:19 386:3 407:14,20 411:2 awareness 309:4	235:4 245:3 271:5 274:11 277:1 283:17 291:20 297:5 310:16 322:1,7 342:9 347:20 350:15 354:14 354:16 369:7 372:21 373:1 383:21 391:9 403:3 background 39:18 216:7 backwards 130:1 bacteria 366:24 balance 220:21 ballpark 19:15 66:5 116:24 124:6 131:16 307:9 baltimore 11:9 barr 2:8 base 54:16,18 57:18 146:5 153:14 266:18 377:15 based 40:22 42:11 54:19 55:21 56:3 69:21 178:4 206:18 225:13 251:15 264:7 266:18 275:4 302:3 338:4 349:2 358:14 360:21 363:1 377:7,13 378:9 379:16,23 baseline 388:8 bases 386:10 basic 218:23 basically 106:9 278:16 303:23

Marc Toggia, M.D.

Page 424

352:4	180:3 186:6	95:21 96:24	140:9 185:23	211:16,19
basing 197:6	195:12,19,22	99:9 103:24	216:4 251:18	240:4 251:16
basis 110:23	213:14 214:24	105:6 106:18	272:1,2 314:2	253:12 256:23
111:23 155:19	229:17,23	109:9 133:17	391:13	265:4 284:12
165:18 181:23	235:3 258:11	181:22 206:23	bladder 114:14	284:22 285:11
245:21 259:10	259:19,22	242:20 281:3	115:4 116:19	289:8,21 354:3
279:22 284:23	272:17,18	297:11 362:14	117:6,10,20	354:5 385:7
285:6 309:18	273:24 274:13	372:3,18	121:3,11 122:4	bodys 205:16
bates 6:11 228:3	279:18 280:2,4	better 84:14,15	122:6,8,12,14	books 316:15
284:8 289:4	280:21 281:7	144:11 375:13	122:19,22	bottom 88:22
298:20 299:1,3	281:23 286:5	389:20 390:12	123:19 130:15	351:16 361:11
321:11,11	288:13,15,22	beyond 187:12	179:24 185:13	384:20,21
bathroom	289:14 291:5,7	248:11 295:21	189:10 268:9	395:17,18
270:10,19	297:18,20	319:18 414:1	275:8 337:23	boulevard 4:4
bcope 4:6	298:6 300:18	bias 80:11	389:1	bowel 180:23
beach 7:8 314:9	305:13 310:10	225:18,18	blaivas 34:14,17	389:1
becoming 233:5	318:21 322:11	226:17 329:19	38:16	box 277:10,15
began 58:17	324:16 327:23	345:7 356:7,8	blaivass 373:5	277:16 278:24
81:6 112:8	330:21 332:19	biases 224:23,24	bleeding 116:14	280:17
317:22 342:9	334:3,17 335:5	biddle 3:14	180:7,9 275:9	boxes 22:14,20
beginning 77:8	335:10 345:14	bidirectional	336:14 337:17	break 24:20
82:19 85:20	345:16 346:23	284:10,20	388:15,17	29:10,11 85:6
88:22 150:20	347:7,15 353:9	285:9,15	blood 114:14	85:8 128:18
245:2 279:15	359:11 361:7	big 104:17	blow 105:10	150:11 151:1
294:9 321:24	365:15 369:9	bill 302:15,17	blunt 411:18	270:9,18
begins 403:12	370:15 374:19	billed 29:5,8	blurred 61:8	279:15 391:14
behaves 247:10	374:21 376:3	billing 25:4	board 10:24	breakdown
253:8,11	378:8 379:23	66:19 67:5,8,9	11:3,6 29:4	116:14
256:22 285:18	381:15,24	69:19	213:1 401:22	breanne 4:4
behaving 135:5	382:2 384:24	bills 27:16	bodies 149:18	bridge 140:13
135:7	410:17	binder 354:8,11	204:17	bridgeside 4:4
behavior 251:5	belong 341:18	binders 330:22	body 133:22	bridging 262:19
behavioral	bench 37:19	biochemistry	134:1,20 135:5	262:23
376:7	38:22 363:24	141:14	135:7,19	brief 24:19
beings 410:2	beneath 365:5	biocompatible	136:19 139:2	85:16 150:16
412:20	benefit 220:22	198:11,12	140:2 142:24	244:22 271:1
believe 26:10	221:2,7	258:14 259:11	147:9 151:8,8	309:1 321:20
31:5 44:8,9	benefits 113:18	359:15,17	151:11,21,21	bring 22:3 23:18
46:6,12 58:16	benign 408:1	biomechanic	152:2,12	25:4 51:11,20
59:8 72:22	bennett 3:6	198:10	177:22 189:24	52:11,12
74:23 75:1	best 19:12 20:16	biopsies 137:7	190:6 193:11	broad 185:23
77:17 78:11	21:22 22:9	biopsying	197:11 202:6	200:4
81:21 83:1	24:1,1 35:16	138:20	202:10,14,19	broadly 220:16
108:22 111:10	60:21 65:18	birth 14:3	203:13,18	379:9
120:5 137:5	70:8 74:1	bit 14:13 29:11	204:14,18	brought 22:8,10
143:17 152:24	75:21 76:1	58:13 72:1	205:8,13,14	22:14,22 23:10
153:5,9 163:2	80:23 83:16	77:1 129:9	206:8,11,16	23:14 24:22

Marc Toggia, M.D.

Page 425

25:21 26:14	calculate 358:13	359:20	399:4,13 400:5	144:8 297:5
27:16 51:8	call 30:13 64:5,6	capacity 251:10	400:6,16,16,18	307:17 308:19
148:19 277:7	82:8 90:19	251:11	400:24 401:1,5	317:14 327:17
278:10 326:8	109:11 294:9	caption 1:20 2:1	casecontrolled	329:13 336:21
327:2 347:21	368:2,8 376:23	2:24 3:1	355:17 358:14	350:19 367:2
brubaker	389:8 390:13	capture 32:15	cases 1:6 19:17	368:14 369:18
405:11,16	called 11:19	69:20 170:14	20:1,3,11,13	373:9 379:16
bryn 16:3,13	74:24 75:1	170:16 330:2	61:2 129:18	certificate 416:1
bulk 13:13 93:7	81:5,11 82:16	captured 93:7	156:14 181:11	certification 9:4
360:13	225:9 249:16	171:22 172:2	337:11 362:21	29:4 416:17
bummer 104:17	calling 82:13	carbon 348:12	categorized	certified 3:19
bunch 22:4,11	87:5	348:13	411:2,3	10:24 11:3,6
248:14 324:12	calls 94:14 102:4	carcinogenesis	category 411:6	416:11
367:6	102:5 111:2	362:23	cause 208:18	certify 416:4
burch 115:17	112:2 148:16	card 87:3	226:2 243:4	419:3
116:10,17	149:20 355:16	cardboard	356:15 363:13	certifying
117:3,7,11,22	406:14	277:10	caused 112:19	416:21
118:2,4,8,14	campus 314:24	care 13:6 14:16	152:2	cetera 130:12
118:22 120:1	canada 170:14	14:23 15:3,8	causes 151:11	234:18,18,19
122:15 123:22	171:3 329:23	15:12 46:10	241:5 260:11	309:22
124:4,8,10	cancer 243:4	49:18 128:12	cautery 290:6	chain 88:10
184:20 185:11	361:4 363:14	153:1 157:20	cell 86:9,10,21	101:7,23 103:8
212:13 216:1,3	390:5	216:14,15	86:24 87:1,6	challenging
217:18,20	cant 23:22 29:16	286:19 287:4	cells 258:18	403:18
218:10,16	43:17 56:10,19	337:5 407:6	center 4:11	chance 21:8,16
219:2 266:6,20	57:3 59:9 61:4	career 28:20	11:11 16:3,12	42:24 386:23
268:4,6 340:2	61:5 69:17	carefully 417:4	16:19,20 218:7	396:10
340:10 342:21	70:9 71:4	caring 242:10	224:2	change 106:3,12
343:2,14,24	79:20 81:22	carolina 4:5	centimeter	136:13 141:6,7
359:24 360:6	82:19 83:7	carried 286:9	55:22 265:11	149:13 258:22
375:8,12	86:19,23 88:13	carries 67:14	265:17,17	272:6 283:1
388:24 389:21	93:24 102:20	carry 115:4,5	centimeters	418:3
burches 185:12	109:18 115:2	carrying 254:15	265:14	changed 271:18
375:2	124:14 125:20	case 10:12 25:22	certain 69:20	297:21
burgoyne 3:5	145:18 154:7	27:17 28:1,8	70:16 116:11	changes 104:19
burt 4:10,13	224:6 241:15	28:12 30:6,21	134:17 141:2	105:22 153:16
167:5	256:3 261:3	33:9 37:19	217:9 235:9	259:4 348:8,24
business 87:3,5	269:16 272:8	89:11 90:6	244:11 245:9	350:4,6 417:11
311:21 312:10	280:23 285:22	111:11 188:3,7	263:11,22	419:5
313:7 314:5,18	289:16 299:14	188:8 202:5	271:24 274:15	changing 141:5
butler 4:10	304:23 312:13	206:15 210:6	345:11 356:13	182:13 367:3
butlersnow 4:13	313:6 317:3,3	226:1 240:21	414:1	channels 310:8
	317:4 320:24	290:2 297:3	certainly 29:2	characteristics
	320:24 324:8	316:23 355:19	60:10 66:24	365:16
C	349:2 351:6,7	355:22 356:1,4	76:12,22 95:3	characterize
cadaver 62:2	358:3 406:6	357:13,13,16	113:15 134:10	76:9
307:8,14,16	capability	358:16 362:16	134:20 141:1	charge 36:6
calcium 240:1				

Marc Toggia, M.D.

Page 426

charged 307:1	chronic 15:3	189:11 234:22	232:13 238:18	398:24
charleston 1:2	140:5 151:7,11	clarity 272:2	244:2 247:15	codes 69:21
chart 7:13	152:2,12	classical 381:10	247:17 251:11	cody 121:5
163:14 326:15	154:17 155:5	classification	255:1 259:7	cohesive 339:15
charts 67:13,16	155:12 156:12	259:15 404:15	261:22 282:12	cohort 234:2,15
158:8,13	177:18,22	404:16	302:19 304:16	332:18
cheap 300:24	178:7,14 202:6	classified 17:12	304:20 310:5	collaboration
301:4,11	202:9,13,15,16	202:13 259:14	310:11 324:8	7:20 383:12
check 215:7	202:19 203:11	413:9	345:18 347:18	collagen 259:3
310:19	204:14,18	classify 55:20	350:17 353:19	263:5,5,23
checked 310:20	205:8 206:7,10	294:8	354:4,6 357:7	collapse 260:12
checking 310:23	206:15 207:1,3	clave 192:22	357:20,21	367:7
checkup 155:23	240:22 353:5	346:13,24	363:1 376:2	colleague 313:3
checkups 14:2	353:20 387:2	347:10,15	379:2 386:7	colleagues 59:4
chemical 136:13	387:14	348:2 349:8,15	397:15 406:16	59:18 60:13
136:14 137:10	chronically	clean 24:5	414:12	307:5 382:4
138:8 139:12	205:14	clear 32:23	clinically 38:20	384:7
139:20 140:1,6	cin 100:10	37:18 45:2	135:15 153:11	colposuspension
140:21 141:3	cindy 6:6 7:11	49:12 53:13	191:8 205:21	121:12 122:6
141:11,14	99:21 100:7	62:5 63:1	206:18 211:21	122:16
347:5 348:7	101:13 103:9	112:14 135:10	242:13 247:21	column 174:1
chemist 141:12	320:3	136:6 161:2	255:23 258:11	com 1:24 4:6,6
141:17,22	circumstances	207:11 211:6	303:21 351:7	4:13
238:8	171:18 247:12	272:19 273:6	360:16 368:15	combination
chemistry 142:1	252:8	339:15 396:12	clinicallybased	72:18 218:19
142:5,7 349:7	citation 33:7	cleared 408:20	135:20	410:2
cherry 3:15	cite 325:17	408:22,22	clinics 363:5	combine 333:18
cheshire 3:4	363:3 367:17	409:5 410:16	clinton 372:24	come 13:11 34:2
chicago 105:10	cited 128:7	410:22 411:5,8	close 59:18	34:11 59:23
children 17:17	189:24 192:22	clearly 47:9	170:7 210:8	60:4 64:23
17:20 18:3,7	324:12 332:2	73:17 97:12	260:12 284:1	66:12 113:19
18:12 372:5	359:10	371:20	closed 170:8,13	156:19 157:9
china 223:22	citizen 409:3	cleveland 363:5	323:13 329:2,8	166:16 169:17
chlorine 239:22	claim 23:22	clients 105:2	closely 160:18	218:22 222:12
240:2	407:22	clinical 6:13	closer 307:11	223:20,21
choice 118:6	claiming 408:23	11:23 23:14	closest 371:17	233:9 329:19
362:20	claims 20:8	38:3 39:11	cloth 254:22	352:11 371:1,4
choices 113:12	30:23 42:14	47:17 48:22	cms 317:17	389:11 391:15
choose 57:2	362:3 385:21	79:6 135:12,22	cochrane 7:20	408:7 412:12
choosing 15:15	387:12	158:8,13	121:4,6 332:24	comes 13:14
chose 357:1	clamped 364:12	192:15,16	333:5,13 334:6	77:1 143:8
392:14 402:3	clarified 311:15	202:11 203:1	334:16 373:3,7	365:11 390:23
christine 91:12	clarify 15:3	204:5 205:24	373:14,21	comfortable
91:21 93:17	40:20 125:14	206:13,19,19	374:16 383:11	90:7,10 371:9
98:24 371:12	168:22 174:24	207:9,9,21,22	384:2,5,10	389:14
chromates	216:6 321:9	219:12,24	392:16 393:1	coming 233:13
239:23	clarifying 56:1	220:3,11 231:8	393:23 396:16	319:21

Marc Toggia, M.D.

Page 427

commencing 3:17	company 31:7 63:20 64:2	280:14	340:1,10	concluded 415:10
comment 30:23 48:6,24 175:16	71:7 86:24	completed 306:7	342:20 374:13	concludes 415:5
176:17 227:1	105:8 108:3	completely 13:17 31:16	385:3,13,23	conclusion 174:23 176:2
236:15 261:5	109:22,23,24	39:8 53:19	386:8 387:8,14	176:18 177:6
348:5 371:19	274:1,14 315:1	71:6 313:12	388:13 403:17	360:21 363:11
385:7 406:23	319:19 320:10	completeness 285:2	404:9,15	374:5 396:15
commented 163:3 268:7	354:11	complicate 129:22	413:13,18,23	397:4 405:7
comments 312:1 320:23	comparable 388:5	complicated 412:8	comply 24:2	conclusions 38:4
commission 419:12	comparative 394:15 395:16	complication 126:1,7,15,15	component 240:14	39:11 163:4
committed 210:12 230:7	comparatively 174:21	127:2 128:8,10	composite 362:5	175:7,13,18,23
committee 323:18 341:21	compare 78:6 80:9 116:7	128:13 131:3	391:16	176:10,12,16
committees 316:2 317:9	375:6,11	169:4 171:16	composition 136:1 137:10	192:16 195:1
common 116:12 116:16,21	398:11	172:1 175:2	138:9 143:9	377:13 396:6
117:5,9,10	compared 121:12 125:21	179:22 336:3	362:4	396:21 404:8
118:6 125:6,8	174:18 335:1	336:11 337:21	compound 14:7	404:19
179:22 185:9	357:9 381:9	338:6 358:8,9	136:14 141:6,8	condition 14:12
275:6 300:12	388:24 395:7	358:21 385:12	141:9 348:14	14:14 189:19
373:23 382:8	comparing 77:5 80:3 174:8,10	399:5,11 400:3	348:16 399:17	190:18 390:20
commonly 117:22,24	388:16	400:7,19 401:6	compounds 145:19 240:3	conditions 202:4
118:4 180:10	comparison 375:18 385:1	complications 44:13 46:4,23	comprised 144:18	345:9 387:3
264:24 266:16	394:23	47:21 48:8,24	compromise 140:14	conduct 373:18
379:15 381:22	comparisons 333:20	50:8,11,24	concede 201:2	conducted 252:23
commonplace 113:14	compensated 293:6	68:2,5,22	concentrated 239:24	conducting 327:5 344:23
communicate 59:19 250:4	compensation 12:12	69:13,20	concentrations 240:9	conference 22:15
269:7,10	competing 312:23	124:22 126:12	concept 73:2	confident 43:8
communication 246:13	complain 311:21	126:13,20	75:6,7 304:20	43:10 58:9,12
communicatio... 51:16 324:1	complains 390:17	127:7,8,17,18	348:14	configuration 361:20 367:4
community 314:16,23	complaint 31:5 390:16	127:22,24	concern 156:20	confirm 349:2
337:4,5	complaints 176:3	129:13 131:5	166:5 191:7	349:10 384:1
comorbid 345:9	complete 188:10 189:4 280:3,10	131:16 162:14	226:3 251:12	confirmed 203:2
companies 223:23		169:9 172:11	concerned 103:6	344:15 352:24
		172:20 173:15	109:23	conflict 316:4
		174:3,17 175:3	concerning 51:17 323:24	317:20
		177:8 179:8,10	351:17 352:16	conflicts 43:20
		179:14,21	404:6	conform 398:7
		181:9,16 184:4	concerns 135:12	confused 52:1
		184:11,19	138:14 214:13	confusion 236:6
		185:1,19 221:7	329:13,18	connected 102:18 233:20
		329:15 331:7	362:12,23	233:21
		334:1,7 335:20		connection
		336:17 337:15		

Marc Toggia, M.D.

Page 428

102:21	constructive	165:1,17 166:2	299:6,10 321:8	255:13 262:15
conscious	339:22	166:16 194:1	copied 22:17	272:16 287:7
287:10	consult 63:19	continued 1:20	copy 24:23	289:12,15,22
consent 79:14	consultant 7:6	2:1,24 3:1	26:11,14	299:23 345:17
79:16 112:10	74:2 75:22	contract 229:9	296:16	349:24 352:5
220:6	292:2 300:6	229:24 233:17	cordial 314:3	353:14 355:11
consequence	303:6 316:14	292:19 293:1	correct 11:5	361:11 363:16
354:4	consultants	295:8 296:16	12:10,21 19:24	366:5 367:21
conservative	315:22	297:18	22:20 25:24	369:16,17
389:13	consulted 71:19	contracts 258:4	29:6 30:3,14	392:18 393:2
consider 12:22	72:9,21 74:19	316:12	31:22,23 33:10	395:5,10 398:1
13:19 16:15	consulting 6:20	contractual	34:19 40:17	399:6 401:7
36:21 37:2,20	296:10	318:7	41:22 50:3	402:4,5 403:20
41:19 57:5,8	contact 30:11	contrary 196:3	54:3 58:18	406:21 408:24
87:7 141:16,24	86:4,8,9 87:2	255:15	59:6 62:15	419:4
142:4,6 144:12	155:20 165:18	contrast 203:3	66:13 72:23	corrected 178:2
256:4 355:16	166:23 167:11	contributed	73:11 74:12,14	correction 26:17
399:24 408:13	167:21	52:6,8,14	77:6,7 84:4,5	339:1
409:13	contacted 30:5	397:11	90:11,12	corrections
considerations	157:13 160:14	contributing	100:22 101:9	417:5,7 419:5
190:3	160:15 162:9	397:11	101:18,20	corrective 182:7
considered	164:19 342:1	control 14:3	121:21 122:4	correctly 12:3
37:15 184:1	contain 67:3	36:23 219:17	123:1 126:2,8	15:8 91:16
195:10 231:8	contained 22:13	323:8 325:2	138:21,22	92:3 99:8
259:6 347:16	33:17 89:2	328:6 333:1,17	161:17 162:10	168:23 175:8
376:14 399:15	115:12	343:9 345:5	162:11 164:21	175:14,19
410:18 412:19	contents 277:16	353:11 356:5	164:22 167:1	176:9,10 177:4
considering	context 89:12,23	356:12,19	169:11,14	358:23 394:6
77:21 126:5	92:23 93:3	357:1,6,10	171:21 172:14	394:10,12
335:2 342:10	94:1 109:13	379:4 384:16	172:22 173:20	397:4,18
consist 332:2	110:16 111:20	392:3 416:20	174:21 177:14	404:18 405:1,3
consisted 357:2	113:10 114:2	controlled	181:18 183:12	413:12
consistency	127:4 144:1	355:20,22	187:21 188:1	correlates
328:8,10,13	146:18 153:7	356:1,4 357:14	188:16 189:15	405:21
344:19 359:5	153:13 185:5	398:17	203:19 208:7	corresponded
consistent 152:4	203:13 207:23	conversation	212:14,15,17	309:9
198:3 306:14	212:4 220:13	60:2 93:6 94:8	212:18,21,22	correspondence
328:19 330:11	220:19 229:2	218:18	213:16,18	30:10 93:14
335:18 344:12	240:5 254:9	conversely	217:15,22	costs 166:17
377:23 386:3	257:9 285:21	180:17	218:5 219:12	cough 288:4
consistently	295:2 311:17	conversing 79:3	219:17,18	390:23
386:9 387:9	312:15 320:16	conveyed	220:6,12,17	couldnt 19:9
consists 16:2	326:2 337:12	376:11	221:13,18,21	82:10 89:22
consort 397:16	362:21 371:10	cook 2:10	222:4,6 225:19	288:5 297:14
constitute 37:2	continent	copay 166:17	225:20,23	counsel 9:3,22
constraints	140:11,23	cope 4:4 193:15	233:6 234:4	31:22 104:20
225:3	continue 156:14	282:18 298:22	238:11 246:19	151:11 187:7

Marc Toggia, M.D.

Page 429

329:7 330:13	174:17 217:23	377:2	367:19 368:8	deemed 216:15
331:3 335:22	221:2 258:13	currently 11:8	372:22 373:2	401:6,10,13
336:16 338:10	286:21 288:23	15:21,22 65:6	374:3,7 375:1	417:19
345:13,23	292:23 317:11	65:11 83:23	375:11,14	defect 18:5
347:22 355:1	321:3 328:2	217:7 218:12	378:11 379:5	defective 36:18
358:18 363:17	courses 250:23	374:9 381:21	379:17 385:19	defects 42:15
363:21 366:4	271:14 272:16	curriculum	387:11 391:23	defendant 4:13
367:5 369:22	court 1:1 9:19	26:19	404:5 405:20	defense 20:10
372:16 392:14	9:24 97:17	cut 159:21	406:11	define 136:12
402:3	98:14 119:19	245:14 246:6	database 344:21	188:5,5
counseled	138:4 164:8	247:9 248:21	databases 67:2	defined 224:22
105:23 114:8	417:20	250:19 262:18	date 3:18 9:14	defines 136:8
counselor 28:18	courtrooms	269:20	27:22 28:8	definition 134:6
29:8 33:11	42:19	cutting 228:14	79:5 101:4	188:13,17
35:24 45:18	covered 97:24	cytotoxicity	215:7 300:24	198:12 249:18
47:8,22 49:11	crack 350:21	385:21	417:9 419:8	249:19 349:24
53:16 58:11	cracking 414:11		dated 7:6 105:16	352:18 355:20
69:16 83:6	create 151:20	D	109:21 303:6	408:10 409:16
95:8 97:11	created 42:10	dameron 2:3	416:11	409:18 410:6
118:21 119:7	creates 151:7	daniel 1:11	dates 82:11	410:13 412:1
122:20 126:23	152:12 177:18	data 6:15 37:7	88:17	413:2
128:15 133:13	creation 145:21	39:9 40:24	day 66:23 74:9	definitions
135:3 138:22	criteria 235:9	66:19 76:4,13	102:16 279:20	126:19
159:16 160:3,7	378:4 398:8	77:1,9,11,17	301:10 307:18	degradation
175:20 189:21	critical 405:12	77:20 78:2,22	419:11	134:2,7 135:22
192:8 194:3	cups 254:22	121:7,9 135:9	days 130:2	136:9,12 137:7
201:10 207:6	cure 385:2	135:10 171:19	216:16 417:16	138:15 139:13
231:1,17 236:4	cured 15:17	171:20 179:2	de 404:2	139:14,15,21
260:18 351:20	156:18 165:15	181:5 190:22	deal 76:10	140:1,6,21,21
399:9 403:2	165:22	191:6 192:12	dealing 336:10	141:3,11
405:5 410:11	curing 390:5	192:13,16	death 207:14	142:13,16,22
412:7	curious 95:14	213:4 215:19	208:1,4,17,18	143:6,7,14,21
counsels 161:8	96:22	221:17 225:15	deaths 131:18	144:6 291:2
322:9 355:6	curl 254:8	225:16 238:6,9	132:9,15	345:14,22
count 192:13	261:16 262:7	239:4,8,15	133:15 207:24	346:3 348:7
countries	curled 261:18	253:17 279:5	decades 222:11	350:1,23
223:20 329:24	262:10	323:10,13	decide 225:21	351:18 352:17
couple 45:8	curling 254:1	324:7 329:21	decided 304:17	352:18 385:21
174:1 222:24	256:6 257:2,15	329:21,22	380:19	414:11,13
223:4 291:10	260:11 261:7	330:11 333:18	decisions 219:22	degrade 134:10
course 31:6	262:17 269:1	335:5 342:2,3	220:3	135:1,7 137:3
37:14 44:16,22	269:19 363:18	342:6,7,8	declined 214:11	139:2 414:15
63:4 70:18	367:7	343:11,14	decomposition	degraded
71:13 77:23	curran 213:12	344:19 345:21	240:24	345:16
79:16 100:14	213:24	353:12,17,18	decreased	degrades 133:21
103:14 113:13	current 26:23	359:5,10	337:24	134:1,16,19
129:22 142:11	113:11,12	360:12 361:19	dee 3:18	136:24 140:10

Marc Toggia, M.D.

Page 430

146:11 147:8 147:22 148:13 149:2,7,18 150:5 degrading 135:19 degree 32:24 71:9 141:13 172:3 263:12 329:15 330:2 385:8 delivered 365:5 delivering 254:14 demonstrate 139:24 213:11 332:7 demonstrated 332:12 390:21 demonstrates 138:24 denominator 359:1 department 313:15 depended 147:19 293:10 dependent 55:17 147:15 152:18 181:13 depends 134:5 220:13 deponent 9:21 419:1 deposing 417:16 deposition 1:21 3:11 5:13 8:2 9:16 19:12 20:22 21:5 22:1 29:23 34:12 51:6 90:11 277:17 290:21 373:5 381:2 415:5,9 416:6 417:3,13 417:17,19 depositions 19:6	19:18 20:14 23:17 24:9 33:23 34:12,16 34:23 35:2,22 277:24 278:4 380:16 deps 1:24 derive 38:3 131:22 192:15 derived 12:19 deriving 206:5 describe 23:11 88:9 272:20 273:7 280:6 described 57:11 157:16 351:19 413:7 describing 229:3 266:2 description 5:12 6:4 7:4 265:16 descriptions 211:8,11 descriptor 56:2 deserves 76:15 design 30:24 36:14,18 39:13 42:14 53:19 54:8 55:11 71:20 72:6,13 73:9,13,14 74:6 77:18 104:6 146:18 176:1 192:17 226:24 229:20 231:13,23 232:12 235:8 237:3,5,9,18 258:24 263:3 295:23 325:9 326:6 338:11 339:5,7,9,11 339:19 341:5 347:18 355:19 365:10,12,16 365:19,24 366:8,12	368:18 designated 17:4 designed 73:18 140:16 237:12 237:20 391:18 398:15 designs 345:4 despite 259:24 264:12 detail 43:18 257:11 details 230:8,14 299:17 determination 357:18 determine 56:10 68:1,5,15,24 69:10,13 162:7 163:15 164:18 189:17 202:7 226:22 241:3 241:20 280:20 350:10 357:19 406:10 determined 57:3 64:24 157:6 225:11,12 277:22 393:21 394:1 395:4 396:2,4 determining 68:19 developed 107:2 development 71:23 75:14,17 75:18 77:19 200:3 243:14 developments 365:22 device 39:13 57:4 58:21 61:15 64:13 114:8 115:13 127:15 129:12 129:15 131:20 132:17 144:2 151:3 172:21	177:18 181:10 182:8,16 183:18 190:24 198:9,20 200:2 229:21 233:1 241:9 267:2 271:10 272:13 275:21 276:5 284:9,14 285:12 322:17 323:2 324:10 325:9 326:6 328:22 334:21 336:5,18 338:7 339:11,20 341:6,8 342:4 342:8 344:7 347:1,19 353:8 360:8,17 366:13,18 379:7,7,11 385:9 408:11 408:12,16 409:17,20 410:6,6,19,23 411:3,4,14,20 411:22 412:1 413:3 devices 54:15 64:22 72:16 73:24 74:18 158:4 181:19 183:10 238:8 241:4 266:12 307:24 308:4 360:3,5,7,10 366:16 377:1 384:19 408:14 devoid 38:17 40:5 diagnosis 69:21 202:20 203:19 414:13 didnt 50:21 52:1 52:2 56:21 60:16 63:1 96:9 147:17	148:19 151:15 158:12 159:2 167:4 176:20 191:20 203:23 222:9 247:22 278:11 281:1 302:23 304:16 308:2 310:5 321:10 338:16 345:15 364:13 die 208:14 died 208:23 dies 209:14,20 differ 231:9 differed 176:4 difference 29:21 101:1 115:23 116:1 127:20 186:12 267:13 294:6 409:5 differences 80:5 different 17:6 35:7,10 53:20 62:5 75:9 76:16 82:23 85:5 88:15 93:20 100:11 101:4 102:15 102:16 129:10 134:11 142:2 145:19 161:6 167:8 177:23 189:14 207:5 211:14 226:7 226:10 253:18 253:20 275:21 278:18 293:4 297:22,23 323:17 336:23 338:10,12 342:7 343:22 352:8 359:11 367:19 371:16 378:20 388:16 393:15,16 394:19,23 400:22 404:10
---	---	---	---	---

Marc Toggia, M.D.

Page 431

404:11	192:19 305:13	disruptions	documentations	18:11 19:11
differential	306:8	115:7	38:8	20:7 21:11
306:17	discover 33:19	distance 315:24	documents 8:10	23:5 26:17
differently	discs 241:7	distinguish	22:4,11 23:16	35:6,9,15
112:21	242:11,21	86:20 354:2	31:7 51:15	37:11 38:8
difficult 115:2	discuss 40:1	distracted 109:7	52:13 57:11,17	40:9 44:9
141:1 175:21	47:20 71:14,17	district 1:1,1,6	58:5 244:10	46:12 50:6
difficulty 130:12	129:13 180:4	9:19,20	245:8 248:20	52:15,15,16,17
173:5	289:1 329:11	division 1:2	249:1,7,9,11	53:5,5 54:24
diffuse 105:3	334:5 340:9	divulge 223:15	249:12,14	55:18,20 56:5
digits 336:12	380:19	doctor 15:14,15	259:24 277:24	62:16 63:8,9
dillon 1:12	discussed 47:2	76:3 147:10	323:24 324:13	67:7 71:13
diminished	48:9 50:8,11	162:15 166:14	324:13 325:15	72:3 73:12,12
269:2	50:24 51:2	169:10 178:15	335:22 354:11	78:11,17,20
dindo 404:16	73:1 88:16	208:10 275:16	368:7 369:11	79:1 80:17,18
dinner 276:21	180:8,24 247:8	326:24 353:6	414:10	81:8 83:11,12
300:9,20,21	253:23 254:3	354:13,21	doesnt 47:18	83:13,22 88:13
301:3,21	discusses 47:7	364:5 369:10	122:18 131:1	89:19,19 91:15
309:21	101:19 334:6	383:23 405:4	139:7,15	92:4,4,5,5,23
dinners 105:2	discussing 94:8	doctors 62:12	140:22 143:17	93:4,5 94:1,2,3
dip 317:3	147:3,4 155:7	208:23 219:21	149:2 150:4	94:7,10,10
direct 181:12	194:19 251:17	245:23 246:4	161:10 183:2	96:2,5 100:14
239:13 285:5,5	389:15	246:21 247:2	186:9 192:13	100:20,23
325:8 347:23	discussion 25:14	248:9 250:16	224:12 231:16	101:10 103:15
349:4 416:20	45:15 48:2,3	261:2,4 269:14	231:21 274:19	103:17 104:17
direction 8:5	48:14 86:7	269:17 274:14	298:19 301:4	104:24 107:23
65:21 312:20	93:8 114:20	294:18,22	347:12 350:1	107:24 110:2
directions	120:16 123:11	300:10 370:22	352:19 406:24	110:12,13,13
285:14	137:20 153:6	document 1:6	doing 14:2 63:18	110:14,15
directly 60:11	153:15 168:15	5:14 20:23	65:6 77:22	111:9,10,16,17
324:9 348:5	194:13 199:14	21:17,20 23:11	96:11 106:10	111:21 112:5
365:7	274:7 283:4,13	23:12 41:22,23	118:8,19	118:13,24
directs 200:15	291:16 301:17	44:20 46:13,24	121:13 149:4	119:23 120:9
disagree 41:6	301:19 331:6	47:13 228:10	154:9 166:9	126:24 131:21
108:6 110:24	331:12 369:3	228:13,16	182:7 183:23	132:3,4,13
111:15,23	383:17	230:4,5 232:7	200:22 207:10	133:13 135:2,4
159:15 211:10	discussions	235:4 236:12	218:20 250:23	136:24 141:16
252:4,9,13	153:14 247:6	239:5 272:14	250:23 266:3,6	145:2,3 149:3
401:18,19,20	269:9	299:3,5 321:10	266:19,20,21	149:3 151:9
disc 240:18	disease 15:4	328:4 340:20	266:22 268:4	152:24 153:8
243:3 361:15	53:20,22	340:23 341:2,8	275:2,4 293:11	153:19 157:11
discarded 326:4	188:19	348:2 373:11	313:18 318:4	159:12,21
disclose 225:18	disorder 15:9,17	376:13,17	352:4 371:9	160:24 161:3
318:13	75:10	394:3,6	372:12 417:8	165:11 166:15
disclosed 317:7	disorders 13:7	documentation	dont 13:19	166:23 168:3,7
317:19	19:21 156:12	57:13 66:16	14:21 15:1	170:2 178:10
disclosure	disposal 119:8	158:3	16:15 17:23	182:21 183:13

Marc Toggia, M.D.

Page 432

185:22 187:11	316:19 317:24	373:5 380:20	268:7 282:16	212:24 213:1
187:14 189:20	318:2,8,9,21	381:3 382:13	292:4 304:24	213:11 332:8
191:18 193:21	319:7,20 330:1	405:16	323:6 324:16	332:13 339:7
197:23 200:12	346:23 347:15	drainage 202:17	330:13 344:18	344:17 359:6
200:16 201:9	358:13 361:24	dramatic 101:1	347:7,20	374:17 377:3,7
203:16 208:2,2	369:18 372:10	314:2	348:11 358:18	378:17 385:8
209:12 210:2,5	399:23 402:10	draw 39:11	359:9 369:10	389:20 393:20
211:2 217:6	402:18 405:17	192:15 195:1	374:19 375:23	395:3
218:2,22,24	407:6,6 409:4	324:8 333:19	384:3	eight 131:9
226:12,12,13	410:17 411:1,5	377:12 404:8	early 59:6 76:21	165:4 307:11
227:12,13	412:5 413:24	dredge 74:20	76:21,24	eileen 81:15
229:1 232:4	414:3	drew 375:17	129:15 287:24	84:20
233:19 234:9	double 11:5	drinker 3:14	ears 210:8	eileens 312:11
234:12 235:3	136:21 317:3	drive 4:11 22:19	easier 173:17,18	either 12:14
235:13,16,19	346:2	293:13	easily 173:17,18	56:22 65:21
236:19,21,23	doubt 42:20	drives 6:16	east 223:22	84:24 96:2
236:23 239:1,3	43:23	22:23 278:10	eat 302:15	118:9 223:21
239:3 240:7,7	downstairs 91:4	279:1,9	editor 70:21	245:8,24 267:8
241:6 242:1	91:24 92:12	drop 105:7	222:1,3 223:8	277:23 292:20
245:17,23	370:5 371:15	330:1	226:4,21 227:8	302:2 337:18
246:1,4,17,24	372:2	drs 34:16 229:10	236:9 406:4	360:2 370:17
247:1 248:1,17	dozen 19:11	drug 411:16	407:12	380:23
249:1 250:1,7	82:5	dry 295:6	editorial 401:22	elastic 284:10,20
250:7 251:23	dr 10:10,21	duly 10:4 416:5	editors 7:19	285:9
254:11 255:3	17:14 20:18	duplication	382:23	electron 347:5
255:22 256:15	23:9 25:20	32:24	educated 71:10	349:17 352:10
258:10 260:17	34:14,14,15	uplications	education 63:21	electronic 22:16
262:3 263:19	38:15 59:3,12	33:5	273:6,21 309:3	element 23:24
264:8 265:9,14	59:17 60:1,1,9	durability	314:16,23	365:24 366:8
265:24 268:19	60:12 63:11,15	332:13	educator 73:5	elemental 107:9
269:6 275:16	63:18 85:24	duration 394:20	effect 259:8	112:16 114:11
277:18 278:8	97:18 104:7	dysfunction	314:5 351:10	125:5 275:11
280:18,18	112:22 121:23	114:12 130:18	effective 46:11	366:11,17
285:4,22 286:5	150:24 154:12	180:19 186:2	47:11 49:22	388:13
287:22,22	158:20 159:5	309:5	212:11 220:17	elements 366:21
288:10,10,13	160:17 213:24	dysfunctions	260:24 374:8	elicits 290:18
288:15 290:8,8	228:9 229:7,23	385:4	411:17	eliminate 345:6
294:6,21 296:4	245:6 271:8	dyspareunia	effectively	elliott 34:15,17
297:6 299:17	274:13 277:5	181:6 344:5	140:18	38:16 325:16
299:22 300:12	279:14 282:21		effectiveness	364:10 367:16
301:20 302:8,8	283:19 291:22	E	47:16 78:3	eloquently
302:14,24	311:20 313:2,2	e18 402:7 403:1	79:10 80:5	362:1
304:9,14,14	318:23 321:6	403:11	213:9 328:21	email 5:19 6:5,8
306:24 309:13	322:7 325:16	earlier 72:9	388:12 396:10	7:8,11 86:8,18
312:2,12,13	354:7 364:10	88:12 119:6	effects 393:15	87:17 88:9
313:4 314:4	367:16,18	156:18 165:10	efficacy 77:14	89:13,16 90:2
315:2,12	372:10,11	165:12 180:4	78:9,14,14	90:8,18 97:20

Marc Toggia, M.D.

Page 433

99:8,20 100:3 100:5,6,12,21 101:7,8,12,16 101:22,23 102:2,24 103:5 103:7,8,12,18 104:10 105:15 105:21 108:11 108:15 109:2 109:13,17 110:19,22 312:9,13 314:9 320:2,9,11 369:23 emailed 86:17 emails 86:14,15 88:18 89:2 93:1,22 94:5 102:9 110:18 emphasis 272:1 employed 11:13 305:22 employees 300:1 employer 11:12 employers 316:3 employment 305:20 316:9 316:12 encompasses 216:11 encountered 284:12,22 285:11 ended 170:18 endpoints 225:5 engineering 75:7 engineers 247:7 enormous 144:24 enrolled 79:9 entire 79:15,15 186:18 entitled 103:10 enzymatic 348:8 enzymes 291:4 epidemiologic	240:20 epidemiologists 376:5 episodes 336:14 337:17 equally 118:11 equivalent 212:24 erode 115:7 117:19 erosion 117:6 121:2,22 122:8 122:15,19,24 123:18,22 124:3,8 188:15 189:9 261:9,17 289:10 343:16 353:21 381:8 erosions 117:11 343:4 344:3 396:11 errata 417:6,9 417:12,15 419:6 error 65:20 erythema 202:16 escapes 82:2 especially 37:24 270:4 espousing 367:20 esquire 4:3,4,10 essence 323:17 essentially 79:21 266:13 278:13 establish 350:23 established 47:17 79:22 113:14 243:7 363:2 estimates 65:18 estimation 295:24 296:5 et 1:8,8,9,9,10 1:11,11,12,12 1:13,13,14,15	1:15,16,17,17 1:18 2:2,3,3,4 2:4,5,5,6,6,7,7 2:8,8,9,10,11 2:12,13,14,15 2:15,16,16,17 2:18,18,19,19 2:20,21,22,22 3:2,2,3,4,4,5,5 3:6,6 130:12 234:17,18,19 309:21 333:5 340:14 404:16 eth 6:11,13,15 6:20 7:5,7,10 228:3 238:17 279:4 296:9 303:5 314:8 320:1 ethibond 118:10 ethical 189:21 190:3 ethicon 1:3,8,9 1:10,11,12,13 1:14,15,16,17 1:18 2:2,3,4,5 2:6,7,8,9,10,11 2:12,13,14,15 2:16,17,18,19 2:20,21,22 3:2 3:3,4,5,6 9:19 10:12 29:6 51:11,13 57:10 58:4,15,21 59:12,23 60:8 60:17 61:13,18 62:2,17 63:5 69:23 72:5 73:23 81:3,12 82:9,12,17 84:4,12 102:8 103:7 106:19 106:24 107:16 107:22 145:24 146:2,9,15 147:7,15,21 148:9,13,14,20	149:6 152:10 152:19 178:13 178:18 228:10 229:10 238:7 241:2,19 242:16 244:10 245:8,13,18 246:5,18,22 247:7,20 248:2 248:13,19 249:11,12,16 250:4,11,15 252:1,2,6,23 255:14 256:5 256:16 257:6 259:24 260:6,9 261:1,6 262:4 262:16 268:24 269:7,18,22 271:15 286:1 287:11,20 291:24 292:3 292:16 293:7 294:20 296:2 296:22 297:10 297:19,21 300:1,2,4,10 301:22 302:6 302:10,20 303:1 305:8,15 305:20,23 306:4,13 307:1 307:8 308:23 309:2,20 311:21 312:9 314:15 315:18 317:8,20,22 318:1,4,8,14 318:17,22 320:20 324:1 332:15 338:12 339:19 414:10 ethicons 74:4 246:12 europe 77:18 evaluate 376:6 evaluation	374:23 evaluations 156:1 evening 402:20 event 292:23 events 5:20 87:19 314:16 314:24 393:21 393:24 395:4 396:3,11 398:21 403:20 403:22 eventually 71:3 everybodys 199:21 201:8 402:19 evidence 7:13,14 36:22 37:3,24 38:4,18 39:10 42:12 44:5 116:22 131:14 133:24 134:21 134:24 143:2 143:23 146:22 148:3 151:10 169:2 188:18 191:14,23 194:24 195:3,8 195:9,13 196:2 197:3,9,13,18 205:15,24 206:5,6 207:13 207:22 208:3 211:17,18 219:14,24 229:15 235:12 255:14 260:3 323:5,6 324:7 325:18 326:8 326:14,19 327:1,7,14,15 327:16,18,19 327:20 328:1,9 328:12,15 330:9 332:3,24 341:10 347:11 347:17 353:11
--	--	---	---	--

Marc Toggia, M.D.

Page 434

355:23 357:15 357:22 360:23 361:1 369:12 369:14 373:12 377:2,7,12,20 377:21 379:24 382:10 393:8,9 393:12 396:9 414:20,21 evolved 76:18 exact 55:3 65:17 67:6 72:14 73:11,15 79:19 271:22 279:23 279:24 281:6 exactly 49:13 66:2 97:2,5,13 97:14 200:9 280:5 352:19 374:4 exacts 67:20 exam 210:15 examination 10:7 322:4 392:10 examined 10:5 examining 206:4 example 41:11 61:14 71:18 82:8 83:20 116:9 125:10 128:6 170:9,15 171:23 225:6,8 251:24 252:17 252:18 317:10 337:21,22 356:18 examples 159:17 exceedingly 181:6 excel 297:24 298:24 excellence 376:2 exception 33:18 excluded 329:17	excludes 257:19 257:22 exclusive 64:18 343:7 exclusively 13:5 excuse 55:19 79:6 104:7 105:1 107:11 131:8 156:3 157:4 169:24 169:24 170:7 183:18 188:22 197:17 206:10 218:3,14 223:9 267:6 311:3 328:9 338:22 343:8 388:20 388:22 408:15 executive 341:21 exerted 365:7 exhibit 6:13 20:20 26:2,9 27:10,18 87:16 88:2 99:19 108:14 228:2 231:7 238:16 238:18 277:16 279:3,8 281:13 281:20 283:8 296:8,15 298:11,15 303:4 314:7 319:24 321:13 326:13,18 369:21 380:8 382:12,20 383:10,24 exhibit1 21:4 exhibit2 27:6 exhibit5 373:5 exhibitions 318:20 exhibits 31:8 37:10 278:6 326:11,24 354:19	exist 414:1 existence 30:21 86:11 existing 359:20 exists 37:24 135:13 191:9 225:18 expanded 55:4 349:21 expect 251:23 expected 258:22 263:1 273:20 expenses 300:5 expensive 307:16 experience 38:24 62:8 64:21 113:15 113:18,22 114:3 116:20 129:17 130:20 151:22 171:16 172:24 178:5 180:9 181:4 186:3 187:13 207:9 224:2 273:22 336:19 337:2,9 344:13 344:15 363:1 experienced 68:2,6,22 338:1 experiencing 202:12 expert 5:16 23:16 26:3 30:5,22 34:23 35:2 37:21 38:13,24 73:1 118:17 142:1,5 142:7 144:7,9 144:10,13 154:13 178:17 184:18,23 230:22 260:5 278:23 324:2 354:10 367:10	387:16 408:24 expertise 19:22 338:11 experts 18:12 24:10 31:8 34:13 37:13,13 40:4 158:11 184:2,10,13 185:18 190:1 191:12 193:13 251:17 324:12 325:16 346:13 368:9 376:5 380:16,18 385:20 expires 419:12 explain 36:1 79:21 132:21 184:23 191:24 322:12 352:13 355:13 explanation 92:10,22 110:22 explant 135:4 explanted 210:23 211:1 explicitly 47:14 explore 393:14 exposed 115:22 116:2,4 254:17 exposure 63:3 71:5 115:14,16 115:18,20 117:1 118:14 118:20 119:24 122:11 130:16 189:14 240:23 243:14 261:19 334:13 343:3 343:21 356:16 366:23 exposures 340:1 343:15 expressed 35:13 expulsion 188:9 188:14 189:3,8	extended 254:7 319:18 extends 19:22 extensive 200:4 extensively 146:7 259:21 331:21 extent 225:17 305:19 external 352:8 extrapolate 241:16 extremely 58:11 195:24 199:20 377:17 extrusion 145:21 289:10 eyeball 288:7 <hr/> F <hr/> fabrication 54:23 face 410:11 facetoface 86:7 facilities 16:6 fact 38:13 41:10 46:8 55:21 101:5 106:3 112:17 116:3 137:6 154:15 187:12 190:1 192:21 198:2 203:6 206:22 231:21 243:3 259:1 268:17 332:4 344:12 350:5 362:3 388:1 factor 38:9 293:20 factored 215:20 factors 215:20 fail 417:18 fails 396:13 failure 130:11 188:10 189:5 fair 32:3,13
--	---	--	---	--

Marc Toggia, M.D.

Page 435

63:24 139:19 142:17 241:24 fairly 253:22 306:13 fairness 357:12 falconer 137:4 138:12 139:7 fall 157:12 411:6 familiar 27:20 31:18,19 33:12 38:6 41:21 43:11,15 45:12 57:14 83:24 142:9,9,12 203:5 229:3 230:3 243:10 285:21 333:8 340:21 346:16 367:24 405:10 405:24 407:20 409:1 family 74:10 275:15 301:8 far 22:21 36:2 38:20 53:13 78:18 79:19 113:21 114:2 192:19,20 217:11 218:15 fascia 267:11 268:1 fascial 115:6,18 184:21 185:13 215:17 217:7 219:2 266:3,20 340:11 360:1,7 389:8 faster 107:13 fault 306:1 favor 213:5 fax 1:23 fda 6:7 47:9,14 80:2,21,24 99:22 101:14 101:19 103:7 103:10 104:16 105:13,18,19	105:24 106:2,4 106:9,14 198:4 408:15 410:16 410:22 411:9 411:13,16 fdas 106:11 feasibility 292:8 fed 90:4 feedback 339:22 feel 152:3 166:8 219:11 247:22 248:8 371:9 372:14,23 389:14 390:10 390:10 feelings 255:20 312:6 feeney 5:20 6:9 7:11 82:1 83:14,17 84:3 84:19 87:18 88:10 89:3 90:21 91:3,6 93:2,23 94:14 94:16 97:21 98:18 100:3,7 101:9,13,16 102:13 103:1,6 103:9,19 104:11 107:21 108:12,16 109:2,16 110:19,21 318:24 319:5 319:22 320:3 320:12 369:24 370:16 372:4 fellows 218:1,3 felt 46:11 105:21 271:24 313:6 336:20 375:7 407:12 female 11:1 19:21 39:15 139:2 212:12 222:5 341:15 fewer 374:12	fibroblasts 258:16 fibrosis 262:19 262:23 263:14 fibrous 290:21 field 76:20 144:14 178:17 268:13 336:22 341:15 370:22 376:8 fields 4:16 9:12 185:6 fifteen 294:23 fifth 113:24 figure 68:21 69:16 104:21 131:16 200:9 326:3 figured 68:19 figures 299:16 filaments 265:20 file 1:3 299:4 files 228:20 filing 9:4 final 288:3 finalizing 29:23 finally 380:18 financial 12:11 43:21 306:3 317:8 financially 315:13 find 61:12 71:10 117:15 120:6 121:18 186:23 187:9 201:3 323:5 324:23 328:13 366:16 368:10 371:4 391:23 402:14 fine 24:21 29:18 83:9,9 111:4 128:23 145:3 161:13 166:16 221:3 276:12 276:17 296:19	396:18 finish 160:1 192:7 finkelstein 109:5 110:14 finland 170:12 170:23,24 171:24 finnegan 313:2 313:2 314:4 fired 108:1 first 21:19 30:4 52:23 63:3,10 63:14 71:5 81:6,9,23 82:21 88:23 91:9,16 98:21 105:19 113:13 120:24 127:5 129:6 156:2,2 156:4 163:1 175:12,17 176:2 217:3 231:9 244:2 286:8 292:2 322:11 340:5 346:18 392:13 394:8,8 firsthand 338:5 firstline 79:24 fistula 289:10 fit 274:20 325:18 411:24 fits 413:2 fitzgibbons 7:18 382:23 five 19:15 61:2 128:21 131:11 132:9,22 133:7 133:14 165:3 166:12 225:9 234:16 297:6 fivefold 121:10 fiveplus 359:4 fiveyear 353:17 flash 22:19 flat 255:11,12	262:13,14 floor 13:7 15:9 15:17 17:7 19:21 75:9 156:12 186:1,2 203:9 251:21 309:4 371:14 fluctuance 202:16 fly 294:11 fmprs 222:15 focus 73:1 272:12 292:6 292:22 325:5 347:13 403:9 focused 152:7 272:11 362:3 folks 104:20 105:5,23 106:17 follow 101:8 157:23 160:11 165:1 332:6 350:20 351:21 followed 131:11 191:4 290:20 following 98:15 114:4 119:20 138:5 164:9 175:10 239:20 322:9 329:14 362:8 378:4 397:16 follows 10:5 100:21 275:8 followup 155:18 156:6,22,24 157:8,17 158:3 160:8 161:16 163:12 165:16 166:3,8 322:8 329:16 330:20 392:8 398:20 footnote 377:4 force 255:4 forces 251:3,14 251:19,20
---	--	--	--	--

Marc Toggia, M.D.

Page 436

252:3 254:17 365:6 ford 374:20 384:7 foregoing 416:17 419:3 foreign 151:8,11 151:21 152:2 152:12 177:22 190:6 193:11 197:11,14 202:6,9,13,19 203:13,18 204:14,18 205:8,13 206:8 206:16 211:16 211:18 289:8 289:21 forgive 411:21 form 6:21 9:6 19:1 60:20 103:3 111:4,6 133:9 144:5 154:4,4,7,20 162:18 165:19 167:3 176:14 183:1 185:3 190:9,20 195:5 196:8 198:22 199:5 202:21 204:24 205:11 207:17 208:12 209:2 210:1 212:2 214:18 221:22 226:8 227:10 229:13 231:15 232:15 234:6 235:12 237:7 241:14 241:15 242:8 243:8,19 245:16 246:23 247:24 248:22 252:11 255:17 256:11 257:7 258:5 260:3,15 261:11 262:21	263:18 265:23 269:4,23 274:18 280:19 285:19 287:16 287:22 296:11 298:5 304:7 305:22 310:1 316:7 317:23 324:21 325:24 349:13 361:15 364:2 367:13 367:23 370:8 386:1 398:3 405:15 407:18 412:4 413:5 414:17 419:5 formal 61:6 62:16 63:4,16 64:1 391:2,3 formally 59:12 format 299:1 formation 241:14 259:3 263:6,23 289:11 362:10 former 13:12 formerly 11:19 forming 394:14 forms 145:5 356:8 formulate 36:13 37:8 323:3 formulated 41:9 323:20 formulating 29:9 36:3,19 178:20 376:14 408:6 formulation 38:9 264:22 378:1 fort 4:12 forth 391:9 fortunate 76:19 337:11 fortunately 217:10 323:9	391:17 forward 161:3 foul 210:11 found 32:16 36:4 109:4 139:6 221:19 240:4,10 330:7 337:7 370:18 391:22 411:16 foundation 43:3 44:4 80:16 102:5 108:8 111:3 143:16 146:13 147:12 148:2 152:16 162:18 205:1 205:11 210:1 229:13 243:20 256:12 260:16 261:12 269:5 269:24 275:5 287:17 298:5 327:12 399:17 407:18 410:9 414:17 four 15:23 16:6 61:2 82:22 83:21 156:2,4 165:3 225:9 307:10,12 fourth 371:14 fourweek 157:22 fragments 349:21 frame 82:16 83:18 frank 71:6 frayed 250:20 fraying 248:20 249:3,8,10,13 249:16,18,19 251:1,11 256:6 260:10 261:7 262:17 269:1 269:19 367:8 free 262:8	freely 193:17 253:22 freestanding 16:20 frequency 399:23 405:21 frequent 186:5 245:20 frequently 86:5 399:14 401:7 401:11,13,23 friction 255:7 friday 199:23 402:20 friend 100:16 103:16 371:6 371:11,17,23 friends 94:21 319:16 370:17 friendship 319:18 front 45:20 90:20 106:6 151:12 330:24 354:15 384:10 402:21 frustration 312:1,19 full 287:7 305:19 function 134:9 316:14 functional 351:4 further 72:1 112:5 396:5 415:1 fw 7:9,12 314:10 320:4	general 13:16,20 13:22 14:4,16 37:18 38:12 39:2 52:22,23 117:17 123:19 152:17 173:16 220:15 236:8 236:10 258:7 265:16 275:23 276:4 286:11 286:14,17,22 287:1,7 288:6 295:15 315:5 330:17 400:5 400:17 generally 23:12 23:13 84:10 246:4 generated 375:14 gentleman 81:23 82:2 374:20 geographic 215:20 georgia 209:21 germane 205:20 getting 18:9 112:10 222:10 317:4 ghenn 81:16,18 81:19,19 82:8 84:20 gifts 300:1 gillum 2:18 girlfriend 91:12 91:21 98:24 gist 223:15 give 18:4 21:10 35:17 42:23 44:2 65:19 66:4 73:23 83:7 88:2 92:9 108:11 112:4 117:16 124:14 124:18 137:13 193:20 220:5
---	--	---	--	--

Marc Toggia, M.D.

Page 437

224:6 227:21 231:24 232:4 248:8 272:8 292:7,13 314:23 315:4 318:18 339:18 355:9 370:1,24 391:5,13 given 19:5,11,18 20:14 21:20 39:22 51:17 52:8,14 53:1,7 55:21 60:24 61:7,13 66:2 76:14 229:19 230:22 245:19 315:21 327:16 393:3 416:7 419:4 gives 110:21 giving 40:4 224:11 230:16 glad 311:14 glass 383:4 gmail 4:6 go 14:8 15:14 18:16 22:5 23:10 25:8 35:6,15 39:16 43:4 44:6 51:5 58:2 59:24 66:14,18 67:4 67:17 69:22 81:2 90:15,17 93:10 98:10 100:8 103:17 120:8 121:16 123:5 129:20 137:6,15 144:17 145:4 145:20 147:13 154:7,11,23 157:20 158:20 159:5 160:1 162:6 164:17 168:9 186:23 187:15 188:3	190:10 194:5 199:6 200:12 201:9 204:9,10 214:19 217:11 218:24 229:16 248:16,23 255:18 261:20 261:23 270:9 270:18 273:17 274:2 285:3 297:5 310:7 321:14 335:22 343:18 351:23 354:13,16 355:14 357:22 368:20 372:24 373:1,21 377:18 383:3 390:22 402:6 402:14 404:23 413:16 goal 377:19 goes 44:20 145:9 171:20 225:4 254:22 261:1 295:20 going 22:5 72:16 85:4,9 88:1 89:6 91:17 93:7 97:22 98:1 100:2 103:20 121:3 132:8 136:3,11 136:12 139:9 148:12 161:7 166:7 174:7,9 176:13 193:20 193:24 194:1 196:17 197:4,5 209:15 225:22 227:20 228:11 235:20 244:8 245:6 246:11 248:14,18 258:21 262:7 276:12 282:9 291:22 292:17	296:17 302:2 310:16 313:13 315:6,9 342:9 355:5 371:13 372:7,8 376:19 376:23 393:4,7 402:9,11 405:7 409:15 gold 380:21 381:16 382:16 goldman 363:4 golkow 1:23,24 9:13 good 65:24 66:9 84:11 85:8 104:20 109:8 128:14 341:14 359:19 375:1 398:15 goodwin 1:6 gotten 295:19 312:6 government 376:3 graft 188:19,23 189:18 199:2,2 grandmother 94:22 granulomatous 203:12 great 43:18 76:10 84:23 100:15 103:16 119:10 257:11 399:22 greater 175:5 184:2 greatest 367:2 greg 120:9 201:16 gregory 4:16 9:12 group 125:6 292:6,22 293:22 332:20 356:5,11,13,15 356:19,22	357:2,10 373:14,15,19 373:22 376:4 groups 73:1 107:4,5 179:4 391:21 grow 290:22 grumpy 312:18 guarantee 92:18 119:1 278:18 guess 33:8 81:20 105:18 109:6 123:4 187:20 214:6 231:3 292:13 352:1 377:17 guessing 59:7 83:19 105:17 107:24 guesstimate 293:16 guideline 328:5 377:5 378:4 379:18 guidelines 323:16 328:17 335:13 375:22 376:24 389:18 397:16 gurt 104:24 guy 100:16 103:16 gyn 11:4 13:16 gynecare 55:9 56:11 57:1 58:5 gynecologic 341:14 gynecologist 13:21 14:4,16 95:3 gynecology 11:19 13:20,23 gynemesh 338:17 339:5 339:20	H half 82:5 169:16 216:19 265:17 hand 88:1 100:2 340:3 354:9 376:19 378:6 393:18 handful 51:7 handle 245:20 hands 130:14 179:24 216:24 336:11 337:22 handy 340:6 happen 136:18 167:9 happened 209:21 210:6 300:23 happens 109:8 143:12 156:11 330:3 happy 40:1 53:23 121:17 201:7 221:5 230:23 299:15 391:12 harass 166:7 harassed 372:14 372:17 hard 222:18 336:12 harm 386:9 harmon 2:12 havent 29:5 188:7 297:1 hazards 240:22 head 19:10 69:17 145:19 163:2 311:5 healing 188:10 189:5 heals 258:20 health 94:21 240:22 323:14 409:16 412:2 413:2
---	--	--	--	--

Marc Toggia, M.D.

Page 438

healthcare 11:10,14 15:23 15:24 170:8,11	393:14 399:24 403:15	379:13	85:10	ideal 107:7
hear 97:14 119:11 148:20 148:23 246:18 246:21,22 247:3 262:4 403:8 413:12	higher 105:5 106:17 121:10 157:5 216:4 287:12 288:15 294:2,14 327:20 382:1 389:23	hold 13:23 14:6 42:22 44:1 49:5 95:10,11 111:1 154:19 185:5 196:16 229:12 235:22 261:4 376:16 414:14	hours 28:1,6,7,9 28:11,13,16 29:8,14,20,21 29:21 58:2 93:9,10,11,14 93:15 119:13 119:15 216:12 224:19	ideas 94:18 352:12 identical 185:7 identification 21:1 26:5 27:12 87:22 99:23 108:19 210:17 228:6 238:19 279:6 279:11 281:16 296:12 298:17 303:7 314:12 320:5 326:16 326:21 380:12 382:24 383:15
heard 210:10 heavily 392:18 heavyweight 55:13 56:11 57:2	higherquality 213:4 highest 294:7 295:19 323:4,6 327:6,13,14 328:1 382:9	home 110:10 honest 31:16 39:8 59:22 61:6 94:11 218:13,21 253:9 287:19 292:12 299:13 302:14 304:9 312:2 314:1 315:21	hovers 389:2 human 133:21 147:8 240:4,10 244:1 410:2 412:20 humans 241:5 241:17 243:9 243:15	identify 100:4 115:23 207:2 330:6 343:1,14 ifu 272:19 273:5 289:6 290:16 291:8 339:11 339:15
held 3:13 9:17 help 89:8 90:5 105:2 308:23 helped 312:3 helpful 35:24 helping 309:3 hematoma 344:4 hernia 7:17 258:8 324:12 325:14,15 367:18 369:11 382:21	highly 163:8 172:24 173:1 258:14 259:11 397:14 highquality 36:20 37:7 38:18 40:5 42:12 76:13 133:23 134:15 134:18,23 135:9 136:23 143:1,23 178:21 179:2 181:5 190:22 288:16 332:3 374:1 377:2,11 386:4 387:11	honestly 19:9 59:9 61:4 82:10 83:22 86:23 89:22 109:14 110:12 110:13 111:17 152:24 honesty 115:1 hope 224:21 306:17 hoped 263:3 hopefully 105:8 201:24 hopes 390:6 hoping 117:15 263:11 375:5 hospital 16:1,3,4 16:4,11,11,14 16:16,24 17:3 209:15 314:24 337:7 385:3	hungry 276:13 hurt 255:20 312:3,7 313:7 hypochlorite 239:24 240:1 hypotheses 348:23 351:17 352:16,22,23 hypothesis 349:2,10 hypothesize 191:13 hypothesizing 352:4 hypothetical 148:16 227:14 227:19 232:17 367:6	iii 381:6 ill 34:20 47:15 74:22 88:2 108:11 139:19 139:19 167:14 182:18 187:8 215:6 218:21 232:5 239:13 268:21 283:22 284:19 299:13 302:14 304:8 368:8 370:1 371:3 378:5 410:10 411:7
hey 372:6 high 39:5 71:9 106:21 107:17 131:13,13 155:17 172:3 315:20 330:2,8 337:11 349:18 352:10 373:13 373:24 382:5 385:8,22	hired 309:9 histologic 138:13 202:20 203:19 205:15 210:15 histological 414:13 histologically 190:17 history 331:22	hour 66:23	I id 50:8 66:14 230:23 301:10 326:10 351:20 371:4 412:5 idea 66:9 93:16 93:21 109:14 265:18 309:16	im 9:12 10:10,22 10:24 11:5,13 11:17,22 15:22 18:8,19 22:4 29:10 33:11,11 33:12 34:5,9 36:10 38:14 39:24 42:4,13 45:1,11 49:7 51:21,21,21,24

Marc Toggia, M.D.

Page 439

52:10 53:11,12	162:19 163:22	295:3 296:16	409:22	181:10
53:16,21,23	166:7,16	299:6,15 300:3	implantation	improved 49:23
54:10,11,21	169:22 170:24	300:24 302:7	240:20 290:18	improvement
58:11 60:6	171:9,17	302:23 305:2	implanted 140:2	180:13 389:21
61:12 62:5,9	172:15 175:20	306:5,17,18,24	162:15 203:4	389:24 390:11
62:15 63:8	176:13 177:5	307:21 311:9	205:13 214:12	390:14
68:11,12,20,23	183:3,20,21	311:14,24	243:24	improving
69:1,12 71:10	186:21,24	312:12 315:6,9	implanting	390:6 397:12
71:14,18,24	193:9,18,20,23	315:19,23	155:1 168:4	397:23
72:1 73:5,18	196:16,16	316:22 331:16	169:10 242:11	inappropriate
77:15 78:23	197:4,5,5,8	331:17 340:15	implants 240:18	18:14
79:1,2 81:17	198:24 200:7	340:16 343:18	350:7,14	incidence 62:6
82:5 83:2,6	200:17,18,18	345:20 346:16	implement	118:13 119:24
86:7,16 88:1	200:20,21,22	349:23,24	409:21	131:22,24
89:4,5,12,15	201:7,19	351:20,22,23	implications	151:24 343:21
91:17 94:15,20	206:18 207:10	358:8 367:24	192:15 396:7	358:8,14,20
95:4,13 97:22	208:20 209:15	370:20 372:23	396:21 397:8	359:2
97:24 98:4	216:8 218:14	373:4 376:19	398:14,23	incision 264:4
100:2 103:20	218:18 221:5,5	376:22,23	implicit 192:17	267:10
107:14,23	221:14 222:10	378:18 386:3	implied 141:10	include 28:21
109:6 110:16	223:9 224:11	387:22 392:15	imply 146:3	30:1 31:14
111:5 112:22	226:9 227:20	393:4,7 396:16	implying 92:6	32:18 34:14
112:23 113:2,5	228:11,19	400:6,17,20,23	221:15 249:4	106:3 130:11
114:7 115:1	229:1,3 230:2	402:8,8,11,13	importance	130:11 181:15
118:21 119:5,8	230:2,3 233:11	402:18 403:2,7	76:11 247:17	186:18 188:15
121:17,24	233:12,16,18	403:11 405:7	357:21 365:15	323:7 325:1
122:9,23 123:2	234:12,21	405:24 407:19	important 126:1	401:1 414:22
125:19 126:3	235:17,24	407:19,20	126:8 127:2	included 23:19
127:3,10,11	236:18,18,20	409:1,6,15	195:10 207:13	57:22 289:14
128:1 129:7,16	236:20,21	411:1 414:5	207:24 219:12	334:19
131:24 132:1,8	237:2 243:16	imagine 222:18	219:14,20	includes 198:2
132:8,21,22,24	244:8 245:6	344:11	220:1,4 247:21	295:22 308:15
133:3,6,7,19	246:1,20 250:2	immune 193:10	251:6 259:7	including 23:16
134:17 135:8	250:6,9 252:5	196:3,4 197:10	261:4 327:4,7	58:15 84:12
135:14,17,21	259:13 263:21	197:14,19	344:22 365:19	186:15 219:16
136:3,11,11	266:2,3,4,5,19	immunologic	366:3,3,8	334:9 393:13
138:13 139:8,9	266:20,21,22	190:5,13	388:7 391:10	inclusive 343:8
140:8,8,24	269:9 270:7	198:14,19,24	399:15 401:6	income 12:9,18
141:2 143:22	272:8 273:9,11	353:4,7,13,23	401:11,14	311:22
143:22 145:7	273:11 275:2,3	immunologica...	404:9	incompatibility
146:18 147:1,3	275:15 276:6	190:16	importantly	239:19
147:4 148:22	276:13 280:13	imperative	227:2 351:5	incompatible
149:6 151:12	281:4 282:3	417:14	impractical	239:21
154:2 158:22	284:16 285:20	implant 67:15	280:15	incomplete
158:24 160:19	287:20 290:1	67:17 166:1	impression	227:11,18
160:19,20,21	291:22 292:14	187:22 256:17	355:9	incongruent
161:7,12,20	292:17 294:12	256:18,19	improperly	327:18,19

Marc Toggia, M.D.

Page 440

inconsistent 134:20 385:19 404:7	262:19 269:20 314:17	275:10 343:3 344:4	268:24 269:3,8 269:11,13,18	310:9
inconsistently 404:3	increasing 406:12	infer 247:16 351:6,7 357:20	269:21 270:2,6 287:11,14	institutes 376:2
incontinence 7:15,16,21 13:7 36:16 39:15 47:12 49:20 51:19 52:20 53:15 75:10 80:1 112:20,20 144:3 153:8 155:3 156:10 165:15 173:8 174:16 183:23 191:2 212:5,9 212:12,21 214:11 241:10 255:3 263:10 315:7,9 322:18 322:23 325:12 325:22 327:10 334:12 335:12 344:9 345:2,20 346:22 347:9 347:14 359:15 360:19 361:21 363:15 365:1 366:10,18 368:17 369:16 370:21 371:7 378:13 379:8 380:10,11,20 381:18 382:15 383:14 385:11 385:17 390:15 405:14,23	incredibly 335:17	inference 38:3 39:11 143:3 206:1 324:8 357:23 358:2,4 378:1	288:20 308:7 308:21 310:18 310:23 355:24 358:7 368:8,10 403:24	institutions 12:8 316:18
incontinent 315:8	incumbent 356:3	infiltration 258:18	informed 79:14 112:10 220:5 242:18	instruct 98:2
incorporated 253:11	independent 23:23 40:23 52:17 60:24 78:17 218:8 256:14 261:14 272:9 328:10 341:12 373:15 373:18 378:10	inflammation 177:18 178:8 178:14 205:22 289:11 353:5 353:20,20	informs 167:18	instructing 18:1 18:18,20 98:5
incorporating 290:24	independently 63:6 80:9 106:10 219:1 376:6	inflammatory 188:12 207:3 290:19 407:15 408:1	infrequently 131:1	instruction 280:15
increased 256:7 261:8,17	index 8:2 176:4	influence 287:23	ingrowth 258:16	instructions 6:12 228:4 257:10 271:9 271:13,18,23 272:10,12 279:16 280:3,5 280:7 281:20 283:20 286:8 417:1
	indication 155:2 191:1 241:10 350:18 351:12 408:16	inform 342:19 344:6	initial 30:10 75:7 77:18 99:14 281:4 362:8 387:1	instrument 409:21
	individual 233:4 386:10,12	informal 59:13 61:6 105:1 301:17	initially 163:6 166:10	instruments 364:14
	individually 22:6 345:10	information 71:1 72:4 87:2 112:5 147:7,18 147:22 152:11 152:13,20,22 178:13,19,19 178:22 191:11 191:14 216:21 221:12 240:12 242:4,12,15 245:24 246:5 247:18,23 248:3,10 249:23 250:2 250:10,12,14 250:15,17 255:21,22 256:5,8,14,16 257:4 260:10 260:13 261:6,9 262:16,20	injuries 130:15 344:5 389:1	insult 159:24
	individuals 39:5 224:2 330:4 332:21 373:19 373:23		injury 114:13 115:4,5 116:19 130:21 179:23 180:23,23 275:9	intact 366:1
	induce 259:3 263:22		input 73:19	integral 366:17
	induced 240:19		insertion 348:11 393:15	integration 269:2
	induction 263:4		inside 280:17	integrity 109:11 109:18 134:8
	industry 43:16 43:22 316:5,14 316:20		insignificant 325:7	intend 33:16
	ineffective 313:12		insinuate 96:12	intended 36:15 39:14 46:13 144:2 173:7 185:17 198:9 268:1 322:17 322:21 323:1 325:10,21 327:9 344:8 345:1 346:21 347:8,13 359:14 360:18 363:14 364:21 365:3 366:9 368:13,19 378:12 385:10
	infection 114:16 116:13 128:7,9 128:12 130:19 269:21		insinuated 369:24 370:9	
	infections		insinuating 94:4 insinuation 95:23	
			insistent 270:15 286:24	
			instance 30:2 152:1 353:19	
			institute 11:24	

Marc Toggia, M.D.

Page 441

385:16 409:24 intensive 128:12 intention 276:1 intents 230:12 interaction 370:6 interchangeable 409:9 interchangeably 409:7 intercourse 181:2 interest 29:1 43:20 80:3 304:17 316:4 317:20 373:17 interested 68:18 68:21 275:20 309:3,10 320:13 337:8 399:21 403:24 interesting 406:9 interests 373:23 internal 31:6 67:1 79:18 324:1 394:23 414:10 international 223:18,18 373:19 interpret 227:4 290:8 interpretation 110:24 232:1,5 interpreted 226:11 interpreting 263:20 interrupt 112:23 170:2 interstices 290:23 intervals 404:10 intervening 390:6 intervention	175:4 186:1 interventions 376:9 377:17 interviewing 94:20 intraoperative 121:21 122:2 intravaginal 381:8 intravenous 286:20 introduced 70:24 281:6 356:9 invasive 374:5 375:4,7,9 investigations 362:2 investigator 235:9 237:23 356:9 investigators 232:10 306:23 357:1 invoice 7:6 27:23 300:19 303:6 invoices 5:18 27:11,16 297:8 involve 357:8 involved 20:5,6 60:5 71:19 72:6 73:9,14 74:5 76:24 223:5 224:9 234:11 301:23 310:11 involvement 71:7 72:13 74:7 75:23 244:12 245:10 247:4 254:4 304:10 involves 166:1 264:22 348:11 iquinto 1:10 irb 79:18	irrelevant 243:5 249:23 irritation 241:1 289:7 290:12 isolated 210:6 isolation 156:11 236:13 isomeric 141:6 issue 201:3 250:6 issued 106:4 issues 195:3 361:10 italian 284:4,5,6 itching 356:23 item 246:16 items 51:8,20 itinerary 6:9 108:17 iuga 335:14 iuj 222:3,20 406:3,19 ive 19:11 20:12 26:15 28:5 29:7,7 39:4,22 53:6 66:8 69:8 71:19 113:23 113:24 129:17 165:9 179:16 181:24 184:17 203:7 213:17 223:1 230:9,21 248:12,24 253:15 264:5,6 277:6 287:18 312:2 318:21 337:13 351:1 364:7 377:9 383:23	jones 2:16 joseph 1:5 journal 41:15 222:8 223:18 223:19 406:3,5 406:7 journals 41:13 70:21 226:4 399:14,20 401:14 judge 1:7 18:6 judi 7:8 314:10 jumping 391:6 <hr/> K <hr/> kaiser 170:10,21 170:22 329:23 kath 320:21 kathleen 5:20 6:6,8 7:11 82:1 84:18 87:18 88:10 99:21 100:7 102:13 108:16 318:24 319:5,22 320:2 320:12,22 369:23 370:16 371:6,23 372:4 kathy 83:1 84:6 84:7 keep 65:22 109:7 159:13 257:16 266:1 276:11 kelly 3:2 kept 336:8 365:24 371:22 key 105:2 366:21 kids 94:18 kimmel 11:21 kind 15:11 26:18 72:4 106:24 152:9 181:20 184:14 189:6 190:2 205:23 219:3	224:9 233:12 233:12 247:17 248:16 253:7 254:20 263:10 277:22 279:22 283:24 301:1 309:15 315:24 317:2 339:9 347:16 351:4,9 363:23 kinds 138:16 king 363:4 kits 105:20 106:6,22 107:18 klinge 367:18 380:20 381:4 382:13 knew 96:23 183:6,6 188:24 knitted 55:11 361:22 knock 357:15 knots 265:9 know 15:1 17:4 18:9 22:22 29:1 33:19 35:9 37:11 39:3 42:1,3 43:17 53:5 56:1,6 63:17 66:20,23 67:2 70:16 71:21 72:2 73:12 75:13 76:16 78:20 79:2,21 81:9 83:22 86:10 89:19,19 92:5 93:4,5 94:1,2,10,10 94:22,24 95:2 95:5 97:4 100:20,23 101:10 104:15 104:24 107:8 107:21,23,24 109:6,9 110:8
---	---	--	--	---

Marc Toggia, M.D.

Page 442

110:13,14,15	259:23 260:14	370:21 371:5	lacks 43:3 44:4	185:18
111:17,19	263:19 264:9	371:20,21	102:4 111:2	leads 261:8
112:6 115:15	264:10 265:9	372:7,8,10	143:16 146:13	262:18
116:6,9 130:3	267:24 268:10	375:2 377:10	147:12 148:2	learn 64:8 70:13
131:9,15,23	268:11,14	377:14,15	152:16 210:1	leave 91:13 99:1
132:3,4,13,18	269:3,15,17,22	378:15,24	243:20 356:20	leaves 167:16,17
133:13 135:2,3	270:2,4 271:17	379:16 386:13	lambert 2:9	leaving 109:22
136:24 140:11	272:11 274:15	386:22 387:2	language 79:19	109:23 320:9
143:9 145:2,3	274:23,24	387:24 388:2	284:2 316:13	lectures 51:17
145:7,17,20	275:19,20	389:4,5 390:9	lankenau 7:12	52:14
146:19 147:10	277:18 280:18	390:10 391:5	11:24 16:2,11	led 269:1,20
147:21,23	280:19,21	391:11 396:23	218:7 310:8	374:20
148:7,8,10,11	282:15 284:5	405:17 409:4	320:4	left 96:20 107:22
149:3,8,16,23	284:23 285:4	411:1,5,17	laparoscopic	109:22 119:15
152:14,23	287:8 288:23	413:24	375:1,12	165:2,6,13
153:1 155:15	289:2 293:17	knowing 90:1	laparotomy	166:24 167:12
156:9 157:19	294:16,21	knowledge	116:11,13	255:9 265:4,7
159:13 163:10	295:6 296:4	19:13 20:16	lapitan 121:5	319:19 320:20
166:6,15 176:5	297:7 304:14	21:22 22:10	large 32:24 58:6	354:9 384:21
178:16,23	304:14,20	23:23 24:1	58:8 156:13	384:22
179:1 193:3	307:15 308:6	29:1 61:23	189:24 294:15	legal 23:16
200:5,22	309:11,16,17	70:8 74:1 76:1	392:21	37:11
206:21 208:7	312:7 313:14	80:24 97:1	largely 325:6	length 265:4,6
208:16,22	315:21 316:22	99:9 104:1	larger 55:4	265:19
209:3,10,23	317:17 318:8	149:7 206:23	228:12,16	letter 105:19
210:5,8 211:2	319:7,15,16,20	242:21 251:16	late 385:13	320:14
213:12 215:19	319:21 320:12	281:3 297:11	latency 243:11	letting 309:11
219:6,10	320:14 324:4	308:18 317:15	243:13 268:15	level 7:13,14
220:16,16,18	329:13,24	317:16 362:15	lateral 395:19	36:22 37:3,20
221:24 223:1	336:9,13,14	known 75:10	395:19	37:21,24 38:18
223:23 225:6	337:3,13,14,16	241:13 250:11	launch 63:21	38:21 40:24
226:16,18	339:22 344:13	315:22	70:10 292:5	63:22 71:6
227:13,17	345:4 348:6,12		launched 70:11	92:19 116:22
229:1 230:8,13	348:14,21	L	73:17,21 78:10	124:11 131:13
233:19 234:10	349:15,19	lab 207:10	78:16,24 79:5	134:21 146:21
234:17 235:16	350:3,8,8	210:17 295:5,6	launching 80:14	191:14,23
235:19 236:19	351:2 352:6,9	295:6	law 3:13	192:4,12,13,16
236:21,23,24	352:15,17,21	labeled 67:21,22	lawsuit 238:5	195:2,8,9,13
238:8 242:5	353:18,21	354:11	239:9 244:12	197:18 205:23
243:13 246:16	354:3,14	labeling 249:4	245:11 254:4	206:4,6 207:12
247:1,1,3,12	355:18,19	laboratory	lawyers 420:1	208:2 221:11
248:17 249:1,4	357:12,14,19	240:17 241:16	layer 290:21	241:1 324:7
250:13 251:2	358:11 359:17	labs 62:2 307:8	lead 241:20	325:1 326:14
251:15,17	362:18,22	307:14,16	301:19	326:19 327:1
253:2,13,13	365:4,21	lack 140:4	leadership	327:13,14
254:8,9 255:16	366:15,20	197:19 198:14	341:20	328:15 330:11
256:14 257:6,6	367:1 370:19	353:22 385:12	leading 184:2	332:23 335:4

Marc Toggia, M.D.

Page 443

341:10 342:18 343:11,13 344:19 347:11 353:11 355:23 356:1 357:15 360:22 369:12 373:11 374:3 377:15,16,20 377:21 379:5 384:9,11 392:21 414:19 levels 39:9 219:13,24 323:4,6 327:7 327:15,19,20 328:1,9,11 330:8 332:3 342:7 360:22 361:1 374:1 393:11 414:21 liability 1:4 liberty 71:14,17 lieu 275:21 life 49:23 84:18 129:23 390:7 390:13 lifetime 15:6 light 42:12 74:9 273:21 376:17 409:14 lightweight 55:12,15,24 56:12 57:2,5 57:12,15 58:6 58:7 153:10 332:11 liked 91:13 99:2 250:10 likelihood 386:17 likes 76:4 limit 125:15 limitations 38:2 348:1 358:1 397:10,22 403:13 limited 348:19	349:7 395:16 limiting 404:4,7 line 8:6,6,6,11 8:11,11,16,16 8:20,20,20 11:13 15:23,24 94:7 102:15 129:2 418:3 420:2 line8 8:16 lines 61:8 link 236:16 list 23:20,24 24:8 31:12,17 31:20,21 32:2 32:12,18 33:3 33:5,24 195:20 374:13 listed 1:6 24:3 33:24 34:18 176:16 listen 160:18,22 listening 183:3 listing 280:11 lists 378:5 398:23 literally 166:13 290:11 311:12 literature 30:2 31:10,14 41:2 78:8 131:6,19 132:10,13,14 132:16 133:4,6 133:16 136:17 162:13,20,23 189:24 190:16 190:22 193:3,5 193:10 194:7 194:18 204:15 204:23 205:6 208:21 211:12 278:1 333:16 344:16 363:2 387:7 389:11 litigation 1:4 42:19 little 14:13	29:11 31:17 58:13 77:1 116:16,21 129:9 140:8 180:10 185:23 207:4 209:22 216:4 251:18 253:9 270:15 272:1,2,3 273:12 294:14 312:17 375:22 388:21 396:9 living 370:19 llc 4:3 llp 3:14 4:10 load 251:9 253:21,21 local 240:19 286:10,14,18 287:3,13 289:7 290:12 294:10 locate 137:13 located 16:1 location 17:13 200:9 294:4 locations 294:12 logan 3:14 long 119:8 120:23 216:22 266:4 332:6 363:6 379:9 402:17 longer 84:3 167:19 246:10 260:13 297:16 389:4 399:21 longerterm 344:20 404:13 longest 83:18 longitudinal 36:24 234:13 longterm 78:2 131:10,16 134:21 140:3 146:22 147:2,3 149:24 152:4 179:3 191:3	197:16,17 214:13 240:23 323:12 328:20 328:21 332:13 332:18 344:17 353:12 385:22 386:4,8,13 387:11,14 393:20 394:16 395:3 396:9 398:20 look 24:15,19,23 27:20 34:1 73:2 88:3 101:15 118:13 119:23 130:24 139:6 169:14 179:2 187:3 194:6 211:3 223:21 224:17 225:1 226:15 229:19 238:14 296:18 298:12 313:13 317:2 323:22 327:24 331:9 332:9 333:15 336:1 337:13 342:12 343:6 348:21 349:1 350:2,9 352:14,19 353:18 354:20 355:23 356:14 357:11 369:13 370:12 371:4 384:15,17,19 386:15,22 391:7 402:1 414:4 looked 36:20 37:14 63:14 134:4 152:8 163:14 210:18 210:20,22,24 230:9 253:5,6 277:6,23 297:22 310:21	323:23 324:2,4 324:10 328:8 328:10 332:19 334:24 344:1,4 346:24 349:16 362:2 374:7 377:22 385:1 looking 38:20 67:18 80:4 137:9 138:8,12 141:4 198:24 216:20 220:10 221:10 224:5,5 227:3 232:2 252:23 329:14 329:20 342:16 351:15 354:18 356:21 388:5 392:15,24 looks 27:15 120:10 277:9 361:9 loose 263:24 lose 14:22 losing 160:20 loss 134:8,9 140:13 lost 312:9 lot 40:8 67:18 107:13 160:19 160:23 200:6 219:7 354:15 374:24 loud 89:6 love 179:1 loved 157:21 loving 161:12 low 173:4 181:6 385:11 393:11 lowe 2:2 lower 105:9 293:16 294:4 327:15,18 334:12 355:22 373:12 377:18 377:21 388:22 388:23 414:21
--	--	---	---	---

Marc Toggia, M.D.

Page 444

lowlevel 325:6 347:2	15:10	282:11,16	266:18,19	176:5 201:1
loyalty 85:1	mammograms 14:3	296:11,15	268:12 278:13	206:17 210:5,7
lucente 59:3,13 59:17 60:1,1,9	manage 248:4	298:10,16	279:5 290:6	210:8 226:18
60:12 63:11,15	managed 173:23	303:7 314:11	291:1 303:18	226:19,20
63:19	management 7:16 173:14	320:5 326:15	347:4 349:20	228:24 230:9
luck 109:8	174:5,19 175:1	326:20 373:4	349:22 352:8	231:18,21
lunch 90:6	184:14,19,24	380:12 382:23	360:12 362:4,6	251:20 252:19
lundell 3:3	380:10	383:15	362:19 409:23	262:1 263:7
	manner 80:10	market 72:17	412:10,11	265:10 278:4
M	94:4 257:14	73:3 75:15	materials 6:18	280:13,14
mac 287:5	262:6 267:9,15	308:13	24:8 31:3	287:20 294:1,6
machine 363:24 409:22	288:12 323:20	marketed 72:22	54:23 57:21	295:20 297:2,2
macroporous 54:20 55:10	325:11 364:19	marketscan 329:22	144:7,8 146:6	297:15 301:17
57:6,12,16	manufacturer 410:1	marks 85:20	239:11,20	301:24 306:12
153:10 198:8	manuscript 306:9	150:20 245:2	248:5 277:6,10	306:21 310:3
259:13 260:13	manuscripts 70:20 224:1	321:24	277:12 281:14	313:1 317:12
334:10 359:13	401:23	married 17:14	307:17 354:15	317:13 319:16
361:22 363:13	marc 1:21 3:12	martinez 1:14	385:2 393:17	327:11 336:9
379:19 381:11	5:4,15,17,19	marty 81:22	matney 2:15	346:23 352:6
382:17	6:8,17,18 9:21	82:15	matter 9:18	355:16 359:16
magazine 309:8	10:3,19 20:24	maslynskymil... 3:18 416:10	101:5 140:9,22	362:11 365:2
magic 254:20,21	26:3 87:18	master 1:3	150:4,8 170:17	365:18 376:16
main 11:13	108:16 279:10	material 6:15	214:5 247:5	377:8 378:14
15:23,24 17:9	281:15 419:8	28:19 54:2,14	mature 263:5	379:14 381:20
maintain 15:6	march 88:20	54:19 55:4,8	mawr 16:3,13	387:18 392:1
maintained 385:9	89:17	55:22 56:4,7	maximum 295:9	399:18 401:21
majority 19:19	margaret 4:3	57:9 114:18,24	mcintyre 1:15	408:20,21
22:17 31:20	10:10 193:20	115:12,15,17	md 4:3	409:10 411:1
38:19 39:4	margin 65:20	115:22 116:2	mdl 1:4	meaning 42:5
41:11 125:4	mark 157:22	137:8 140:7,10	meals 302:11,15	84:23 247:15
169:8,16	161:19 277:15	140:13,14,22	mean 13:20	meaningful 37:23
264:20 286:15	277:19 278:8	146:5 147:4,8	17:12 23:1,2	means 134:8
286:16 334:18	278:19 326:10	149:17 150:5	26:15 36:21	167:18 303:22
353:16 393:10	376:20 380:6	153:10 187:23	39:23 62:7	409:11,20
404:14	382:11	189:4 197:14	63:9 64:7	416:19
making 213:22	marked 8:19	198:11 200:1,6	67:20 69:18	meant 183:7
213:24 214:3	21:1,3 26:4,8	203:5 205:17	70:22 74:7	188:24 286:3,6
276:1 403:17	27:11,17 87:21	211:16 214:12	79:12 84:18,22	measures 391:20,21
male 118:23	99:23 108:18	224:10 238:6,9	87:4 89:11,20	mechanical 252:24 350:12
malpractice 20:1,3,7	228:5 238:19	238:14 239:4,8	93:5,9,11	351:4 363:19
mammogram	279:6,11	239:14 241:15	94:15,24 110:4	mechanically 245:14 246:6
	281:16,19	245:19 246:13	115:14 126:10	247:9 248:21
		251:16 253:7	127:1 131:2	250:19 254:6
		253:10 256:22	134:2 141:2	
		257:15 266:15	143:6 144:24	
			145:13 157:2	
			157:18 170:4	

Marc Toggia, M.D.

Page 445

262:18 269:20 mechanics 280:9 media 11:10 medial 395:19 395:20 medical 11:24 16:3,12 20:1,2 20:7,8 38:4 162:3 164:13 172:2 173:14 173:15 174:4 207:1 218:7 251:24 287:9 310:9 360:3,4 408:11,12 409:17,20 410:3,6,19,23 411:3,4,14 412:1,22 413:3 medically 173:23 medicare 215:19 317:18 329:21 medication 80:7 376:7 medicine 11:1 11:20,21 144:13 206:19 220:2,19 222:6 341:16 376:8 meet 90:20 304:16 meeting 300:20 300:21 318:20 meetings 28:23 70:17 300:10 300:15 301:21 302:11 318:18 membership 382:1 memory 30:7 65:24 66:13,14 74:21 230:7 mental 336:13 413:14	mentally 66:9 mention 46:4,22 89:6 96:16 106:16 134:12 mentioned 33:22 72:9 84:13 135:24 157:15 216:18 310:17,22 344:18 352:2 359:9 366:2 367:10 371:24 375:21 387:3 mentions 44:12 mesh 6:11,13,15 6:20 7:5,7,10 20:15 45:22 51:18 52:5,20 53:14,17 54:2 54:14,20 55:1 55:10,15,17 56:10 57:1,6,7 57:11,16 58:14 105:20 106:22 114:18,24 115:12,15 130:16 134:13 134:16,19 135:1,4,6 136:18 138:20 138:21 139:1,1 140:2 142:23 144:1,18 145:5 145:6,11 146:5 148:13 151:3,7 151:20 152:1 152:11 153:3 153:16 154:14 155:2 162:14 162:16 169:3,8 173:19 174:11 174:18 175:2 177:17 184:4 184:11 185:1 185:21 186:16 186:17 187:20 188:6,9 196:5	198:7,20 202:10 204:17 205:7,9,17 206:8 208:24 210:15,23 211:1 214:14 222:23 223:2,5 223:12 224:9 228:3 238:7,17 241:4,20 242:17 245:14 246:6 247:10 248:21 250:20 251:4,8 253:1 254:2,7,8,11 254:14,16,16 254:16,19,24 255:9,11 257:18 258:4,8 258:10,15,21 258:21 259:2,2 259:5,11,14 260:5,12 261:8 261:15,18 262:5,6,9,18 266:12 267:22 269:20 279:4 288:2,11,12 289:20 290:10 290:18,23,24 296:9 303:5 314:8 320:1 331:20 334:10 338:18 339:6 353:8 357:9 359:13 361:22 363:13,19,23 364:12,19 365:5,7 368:2 368:3,3 378:20 379:20 381:12 382:18 meshes 253:18 256:17,18,19 334:14 meshia 381:6 message 288:9	313:8,9 met 232:11 235:10 237:24 378:4 metaanalyses 328:15 359:4 metaanalysis 213:3 323:9 333:10,12,14 340:19 342:13 342:18 384:12 meth 254:13 method 365:13 373:12 395:7 methodologic 325:20 344:24 methodologies 392:2 methodology 36:2 192:11 322:12,15 324:18,23 327:24 348:1 349:3,9 355:2 355:10,13 397:13,24 methods 66:8 301:19 mickey 213:12 213:17 microgram 347:5 microscope 210:23 211:1,4 349:18 microscopy 352:11 mid 382:5 middle 223:22 236:16 354:14 midurethral 7:20 41:20 44:14 45:5,22 46:5,8 47:10 48:9,22 49:17 115:9 124:24 130:5,6 185:14	212:1 215:18 266:23 267:1 331:13 343:22 375:19 381:21 383:12 384:6 388:24 389:19 390:1 394:24 396:24 midurethralsl... 65:4 mild 104:19 105:22 106:2 miles 293:13 miller 2:14 9:24 millions 49:24 mind 34:3,11 79:4 120:10 200:11,16 257:16 266:1 297:15 409:9 minded 391:11 mine 208:14 249:20 282:23 313:3 mini 375:15 minimal 255:7 290:19 359:21 minimally 374:5 375:4,6 minimize 80:11 224:24 225:17 356:7 minor 16:22 33:6 106:12 126:11,14 127:17,22 207:14 minority 350:6 350:22 393:11 minute 88:2 137:13 310:17 330:23 minutes 119:15 128:22 201:7 217:1 291:10 mis 169:14 misdirecting
---	--	---	---	--

Marc Toggia, M.D.

Page 446

312:19	month 223:3	374:20	neighborhood	nonhealing
misread 95:6,8	months 156:3,6	names 74:17	388:10	202:15
96:22	156:8 309:14	82:7	nephelation	nonimportant
misremember...	moral 109:10,18	national 294:11	141:9	208:1
169:15	morality 134:11	329:2 376:1	nerve 180:22	nonphysiologic
misrepresenta...	morbidity	native 184:21	nerves 114:15	247:11,14
411:11,18	373:12	262:9 299:4	neurourology	251:2,14 258:2
misrepresented	mothers 13:12	natural 262:24	392:24	nonresponsive
39:9	motley 4:3	naturally 275:7	never 38:3 74:8	192:24 268:22
missing 405:20	motleyrice 4:6	nature 337:19	75:14 80:13	nonsurgeons
406:11	mount 4:5	390:18	108:2 151:24	275:14
misspoke	mouse 367:19	near 21:21	155:4,11	nonsurgical
218:15	move 48:5 85:5	nearly 178:6	184:17 192:14	212:20 388:3
misstate 353:15	103:21 107:12	necessarily	204:13 206:24	normal 251:8,9
misstates 44:4	172:5,6 177:10	72:19 131:2	210:22,24	normally 240:9
46:18 49:6	177:13,15	209:13 295:5	249:7 254:24	notary 3:19
56:14 136:4	201:7,21	337:6	264:11 289:21	419:14
146:13 148:2	237:16 238:1	necessary 48:23	294:14 315:13	note 24:5 32:9
153:22 154:5	268:21	216:15 417:4	315:20 318:1	34:21 62:3
163:18 182:10	msds 360:12,15	neck 185:13	362:15 399:11	100:11 103:11
229:14 231:15	360:24 361:13	268:9	400:3 403:4	336:13 381:3
235:12 260:3	mthompsonmd	need 15:10 73:3	new 61:14 71:20	noted 9:22
289:24 394:3	4:6	93:3 128:19	78:4 292:8	380:17,21
404:22 413:15	mullens 2:5	165:11 179:19	293:3 309:9	417:11 419:6
misunderstood	mullins 1:8	180:16 184:9	399:5,11 400:3	notes 26:13
123:2 231:3	multicenter	185:6 191:18	400:7,18 401:5	333:3 336:8
400:14	232:24 233:3	208:2 227:24	newer 80:2	413:14 420:1
mix 20:10,12	multifilament	232:4 245:17	106:7 113:17	notice 3:13 5:13
mixed 21:11	334:13 395:21	245:23 246:4	113:19	20:21 21:4,24
model 67:19	multiincision	246:17,21	nice 7:15 198:5	51:6 100:10
moderate	47:16	247:2 248:10	375:22,24	noticed 33:4
393:10,11	multiple 172:13	256:15 257:6	376:1,21,22,23	novara 120:7
modification	172:21 173:9	262:3 278:8	376:24 379:18	340:14
75:3	233:22 330:21	304:18 372:7	380:9	novo 404:2
molecule 145:13	334:6 384:15	387:15 397:9	nielsen 229:11	number 26:9
molecules	multitask	398:15,19	234:14 332:18	27:18 47:9
348:13	118:24	404:6 408:14	nils 4:10	51:10,23 67:19
money 296:22	<hr/>	needed 30:21	nine 165:4	67:19 69:10
309:19 310:6,6	N	184:24 247:22	nitric 143:11	85:21 88:2,5
310:12,13	name 9:11 10:18	272:1	239:23 240:2	117:16 150:21
316:5	75:12,13,16	needle 389:6	nitrous 143:10	156:13 239:14
monitored	81:22,24 82:1	412:13,15,16	nominations	240:11 245:3
286:19 287:3	82:2 83:1	needs 209:13	315:18	281:20 284:9
monofilament	109:4 110:15	356:16 408:16	nonclinical	289:4 294:22
331:20 332:11	224:12,13	negative 136:21	238:23	295:20 298:20
334:10 381:11	299:19 320:19	137:1 206:13	noncontrover...	298:23 299:1,3
382:18 395:20	365:11 370:24	346:2	220:8	299:3 303:9

Marc Toggia, M.D.

Page 447

322:1 331:10 331:19 332:10 343:20 349:8 362:14 371:1 389:12,14 393:12 397:10 397:22 numbered 331:15,17 numbers 86:22 105:8 124:15 124:19 298:7 403:16 numerous 328:6 345:15 359:4	139:3 141:18 143:15 146:12 147:11 148:1 148:15 149:10 149:19 152:15 153:21 154:3,4 154:6,20 158:6 158:18 160:6 162:17 163:17 164:2 167:2 177:19 182:9 185:2 190:8,19 195:6 198:21 199:4 202:22 204:19,24 205:10 207:16 208:8,11 209:11,24 214:17 223:6 229:13 230:20 231:14 232:14 234:5 235:11 235:23 237:6 238:1 242:7,19 252:10,20 260:2 265:22 285:1 289:23 305:21 309:24 318:5 319:2,6 319:13 394:2 395:11 398:2 399:7,16 400:9 401:8,15 404:21 405:8 406:13 407:17 408:3 410:8 413:4 414:16 objections 9:6 153:24 167:13 objective 174:12 224:17,21 225:2,6,15,16 226:23 227:2 391:6,8,20 398:10 objectively 391:19	objectives 176:1 232:11 398:18 objectivity 345:3 obligation 336:20 observation 211:22 219:4 262:3 336:15 350:21 351:9 352:7 374:11 observational 347:2 observations 38:23 338:5 observe 188:2 202:5 353:19 observed 178:7 289:21 350:11 380:17 obstetrical 19:23 obstetrics 11:18 obstructive 200:23 288:12 obtain 307:17 obturator 67:22 72:11 307:22 334:24 384:18 384:21 394:20 395:18 obvious 273:19 obviously 23:22 24:10 37:15 67:8,20 75:2 77:1 93:5 115:14 134:12 157:19 251:21 265:8 288:5 337:10 344:10 371:15 379:14 388:16 402:8 occasional 337:16 occasionally 13:20 312:5 occasions	180:15 occupation 10:20 occur 124:10 129:23 131:2 140:1 142:23 143:3,4 181:9 184:16 255:8 289:9 342:21 350:24 388:14 occurred 25:15 45:16 63:13 69:14 120:17 123:12 133:1 133:12 137:21 168:16 194:14 199:15 208:4 209:18 251:2 268:11 274:8 281:5,9 283:5 283:14 291:17 306:6 349:5 369:4 383:18 occurrence 173:2,4 208:17 406:17 occurring 340:10 362:16 occurs 131:1 139:15 190:24 263:14 264:4,5 264:7 october 1:21 3:9 9:15 416:11 offer 165:22 336:23 348:22 348:23 offered 72:10 355:12 offering 109:24 offhand 294:18 294:21 offhanded 320:23 office 4:11 11:7 66:15,17 86:6 371:14,18	373:20,22 414:4 offices 3:13 oftentimes 19:22 128:7 160:14 223:24 224:3 307:15 371:3 391:2,11 ogah 333:5 334:4,16 372:20 373:3 392:15 396:2 396:15 397:5 397:20 398:23 oh 22:4 34:9 132:12 282:3 299:8 311:3,7 311:11,24 331:1,17 414:8 okay 12:18 17:14 18:24 22:24 32:12 33:15,22 41:18 43:11 47:4 51:24 56:24 63:24 69:5 78:13 79:4 83:3 88:4 89:18 90:17 97:15 99:11,16 102:22 106:16 113:9,10 116:11 119:5 125:17 127:14 128:3 134:14 135:23 136:11 136:15 137:14 149:12 150:3 151:18 152:6 160:23 161:6 162:12 169:11 173:24 177:6 177:10 179:18 186:19 187:8 192:13 193:23 194:20,22 195:18 197:21
--	--	---	---	--

Marc Toggia, M.D.

Page 448

204:12 212:13 213:21 215:6,9 220:23 222:14 224:16 225:16 228:21 236:6 237:16 239:7 244:12,13 247:20 248:13 250:16 256:16 260:9,19 284:19 331:2 333:22 355:5 356:23 366:14 390:5 391:5 395:8 401:4 402:1,24 409:18,19 413:11 olmstead 229:10 230:17 233:1,4 234:10,23 282:12 olmsteads 234:23 once 155:5 183:17 253:11 308:12 377:10 oneonone 250:5 250:8 ones 15:12 16:8 21:11 34:10 81:14 82:6 84:12,15 134:11 157:11 223:21 277:11 301:8 328:7 362:8 374:14 390:6 onetime 62:7 309:18 ongoing 152:12 open 121:12 122:6 operate 16:10 16:13 371:15 388:9 operated 235:2	operating 17:9 295:4 343:4,16 344:2 350:16 operations 7:21 383:13 384:6 opinion 13:22 29:9 36:4,13 36:19 37:8,21 38:10 39:1,3 40:3 50:3,5 55:14 56:9 57:18 73:19 87:13 102:6 115:10 131:6 134:14,24 140:20 143:19 144:5,16 149:14 151:19 154:14 178:20 181:8 189:2 195:2 214:8 243:5 246:3 248:8 249:22 260:4 261:14 262:14,24 266:11 292:7 301:12 323:4 323:20 327:10 341:3 348:22 350:19 353:13 355:12 362:22 366:4 380:3,5 408:7 414:14 opinions 18:4 33:15 34:22 35:1,12,17 39:17,21,23 72:11 73:24 96:4 230:17,22 324:3 339:18 344:7 373:8 376:15 402:4 opportunities 94:19 opposed 115:16 115:18 129:14 357:13	opposite 162:21 168:2 option 289:2 308:16 options 336:24 371:21 oral 61:13 order 251:7 323:3 391:23 organ 51:18 53:14 55:2 174:19 188:16 344:5 organic 348:16 organization 376:4 409:16 412:3 413:3 organizations 316:3 original 21:10 31:5 72:10,21 73:10 75:4 162:15 163:5 168:4 169:5,10 231:11 234:1,9 234:10,23 235:5 258:24 263:3 281:22 297:8 374:23 417:15 originally 69:2 originator 75:6 outcome 263:1 351:5 354:6 356:14,15,17 356:21,23 357:20 outcomes 114:4 393:19 395:2 398:19 403:18 outdated 308:20 outlined 257:11 outpatient 17:2 output 16:23 outside 18:22 90:20 169:17 229:18 365:2	overall 130:13 333:4 359:6 385:15 387:10 388:12 overbroad 14:7 54:5 62:20 68:8 258:6 overt 188:8,14 188:18 189:8 overweight 213:3 oxidation 142:10 151:14 347:23 348:3 349:1,4 351:15 352:23 oxidative 142:13 142:15,22 143:5,7,13,20 144:5 346:3 348:6 oxide 143:10,11 oxidizers 239:22 oxley 1:16 oxygen 143:8 145:9 239:24 348:12	387:21 393:7 402:6 403:1 418:3 420:2 pages 228:14 330:5 361:9 393:4 419:3 paid 12:7 73:23 74:2 75:22 215:10 216:1,9 232:11 233:5 235:9,21 237:23 292:2,9 293:9,22 295:9 295:12 296:2 304:5 305:7 309:20 310:3,4 314:20 315:3 315:12 317:4 317:17 pain 80:7 105:6 106:18,21 107:17 154:17 155:5,12 181:2 202:16 paoli 16:3,11 pap 14:2 15:11 paper 22:17 48:10,12,15 121:18 177:6 181:14 227:8 237:8,10 305:16 328:16 340:4 343:1 346:12,15 349:8,23 351:8 354:18 355:10 358:17 363:3,9 367:17 388:20 405:11 413:19 papers 48:17 131:14 192:18 213:15,18 359:11 363:10 413:22 paperwork 238:23 paradigm
--	--	--	--	---

Marc Toggia, M.D.

Page 449

112:18 paragraph 284:15 331:9 331:15,17,24 332:10 340:9 393:8 394:9,11 396:8,20 397:4 397:17 398:13 403:12 paralegals 32:11 parameters 157:16 paramount 192:10 paraphrase 47:15 parlor 20:6 part 13:15 54:7 72:24 77:4 98:15 119:20 138:5 164:9 220:19 228:12 239:10,11 259:7 271:21 292:6 334:23 392:21 participate 62:1 304:2 339:8 participated 305:5 participating 233:2 participation 305:10 341:24 particular 48:15 79:5 201:3 202:4 224:1 246:15 250:5 256:22 331:23 332:5 345:11 346:21 356:20 364:21 396:24 particularly 271:22 352:22 397:12,23 partner 309:10 pas 75:20	pass 121:11 passage 122:1 122:22 passed 122:5 267:9 passing 122:3 passive 254:16 pathologic 203:19 211:8 pathological 211:11 patience 160:20 patient 13:21 14:12,15 64:23 67:13 79:22 114:6,23 155:11,22 162:8 163:14 164:18 165:13 165:17,22,23 167:16,22 169:23 170:17 173:6 188:21 189:2,23 202:2 202:8 206:24 208:10,13 209:20 286:22 287:6,9 295:5 362:16 371:2 371:12 386:21 390:9 391:12 patients 13:8,11 13:12 14:22,23 15:7,17 17:12 68:5,9,22 79:9 79:12 80:12 106:7,20 107:4 107:6,16 112:9 112:14,24 129:4,14,19 130:2 133:20 149:16,22 151:2,6 152:23 153:2,19 154:16 155:4 155:18 156:11 156:14,16,22	157:8 158:4 160:13 162:5 162:13 164:15 165:2 166:11 166:13,24 167:11 168:3 169:3,8,17 171:15,22 172:10,18 174:11 177:16 178:22,24 179:7,9,13 180:8,11,24 186:7 187:5,14 187:23,24 189:17 204:13 206:12,22 208:23 214:10 217:10 220:5 225:10 234:12 234:15 235:1 242:18 248:4 268:17,18 275:17 289:20 314:17 329:14 329:17 335:21 336:3,9,17,24 343:1 345:7 386:15 403:24 patricia 7:8 314:9 pattern 176:3 pause 196:17 230:23 pausing 20:4 pay 302:10,13 307:2 314:15 paying 316:23 payment 296:23 296:24 payments 316:20 peer 41:2,7,16 peerreviewed 41:13,15 peers 362:13 pelvic 1:4 11:1	13:7 15:9,17 19:21 51:18,18 52:5 53:14,14 53:17 54:2,14 55:2 75:9 156:12 174:19 185:20,22 186:1,2 203:8 203:14 204:17 205:7 222:5 242:17 251:21 289:20 309:4 341:16 pencil 26:16 pending 239:2 pennsylvania 3:16,21 4:12 9:18 11:10 people 83:8 84:18 94:24 95:1 130:14 131:11 157:19 163:4 180:17 247:8 249:15 251:23 288:17 293:19 309:11 313:17 329:24 371:1 373:17 peoples 200:19 percent 65:2,13 65:14 117:18 120:6 121:15 123:21 130:9 130:16,17,18 130:19,22 131:17 153:4 157:5 161:19 163:12 180:1 204:16,21 205:7 206:12 261:21,24,24 381:7,9 382:1 386:11,19,23 387:9 389:3,12 percentage 65:10,12 69:8 216:17	percentile 157:1 157:3 perchlorates 239:23 perfectly 260:21 perforation 121:14 180:22 180:22 337:23 perform 16:8 130:8 217:7 219:1 241:2 251:8 253:14 286:13 373:24 performed 61:2 123:23 179:15 180:16 181:20 186:16 217:14 217:18,19 218:16 219:16 257:13 286:11 286:17 303:20 303:20 344:13 382:8 performing 63:6 181:24 217:4 218:10 275:22 period 83:18,21 130:4 158:1 182:1 243:11 243:14 254:7 271:19 272:7 279:20 294:24 306:15 332:20 363:6 414:1 periodically 271:12 perioperative 374:12 386:10 permanent 115:16 117:2 117:23 166:1 permanganates 240:1 permission 402:14 peroxides 239:22
---	---	---	---	---

Marc Toggia, M.D.

Page 450

202:15	phys 252:14	267:3 268:5	128:14,19	381:12 414:15
person 15:10	physical 17:13	307:24 309:7	130:23 156:17	polytetrafluor...
140:10 293:18	physician 10:22	365:13 366:14	157:14 161:3	125:11
316:23	14:17 95:1	placement	165:21 174:14	poor 348:1
personal 28:24	126:8 147:24	114:17 214:13	181:13 192:21	poorquality
38:24 86:14,18	170:22 242:6	257:18	230:24 292:24	196:1
86:21 87:1	287:14 288:24	places 387:13	294:10 312:17	pop 173:19
94:13 95:2,4	295:3 297:10	placing 215:11	313:11 329:11	175:2
110:19 301:11	297:12 312:24	216:19	332:1 352:23	pore 58:6,8
320:11 337:2,9	317:5 362:12	plaintiff 40:4	361:23 365:20	367:7
personally	physicians	plaintiffs 4:7	396:18	pores 260:11
133:19 158:21	13:10,13,14	10:11 20:10	pointed 193:14	portion 350:17
187:18 289:17	14:21 247:6	31:8 34:13	346:13 358:23	357:8
persons 126:14	256:2,4 257:5	37:13 322:9,13	points 271:24	portions 368:2
140:15	272:15 288:21	324:3,11,17	policies 316:3,19	posed 18:6
pertains 220:20	294:11 309:12	325:16 329:7	polymer 144:10	position 37:5
370:15	312:23 313:14	330:13 331:3	144:13	40:16,21 41:8
pertinent	373:16 376:11	335:21 338:9	polypropylene	41:19 42:7,9
242:13 361:19	physiologic	345:13,23	47:10 54:20	42:18 43:12
364:20	247:11 251:9	346:13 347:22	55:10 57:6	44:12 45:5,12
perused 230:4	251:10,19,20	354:24 355:6	125:16,19	45:21 46:3,7
ph 1:23	252:8 253:3,20	358:17 363:17	133:21,24	48:10,19,20
pharmaceutical	255:4 258:1	363:21 366:4	136:2 139:1	49:13,15,15
93:20	263:13	367:5,10 368:9	140:2 142:23	50:2,4,11,19
phase 76:21	physiologically	369:22 372:16	143:13,20,24	51:1,3 58:10
phenomena	252:3	380:16,18	144:22 145:10	78:7 99:6
190:23 191:9	picked 225:8	385:20 387:15	145:11,12,16	140:15 161:11
phenomenon	picking 275:15	plastic 149:17	145:22,24	288:3,11
135:12 189:14	356:10	pleasant 4:5	146:2,4 151:3	323:16 330:15
290:14	piece 41:2	please 10:17	151:7,20,23	331:5 332:22
philadelphia	267:21 364:12	45:24 97:18	152:1 153:3	333:23 335:3
3:16 9:17 16:2	pieces 37:9	98:12 100:9,14	177:17 187:20	335:11
81:6,12 155:17	piercing 20:5	101:11 103:2	196:5 198:7,19	positioned
184:3 302:2	pike 11:10	103:15 109:11	238:7 240:16	254:18
phone 30:13	pile 354:16	115:24 119:17	240:23 241:4,7	positions 292:20
86:9,22 94:14	392:21	136:21 138:2	241:8 242:16	possession 33:2
100:13,19	pilot 355:17	162:24 168:10	242:21 259:14	41:24 51:9,12
103:13	place 59:5 70:4	192:7 196:10	264:16,23,23	51:14 52:18
phones 86:10,24	215:16 216:23	196:13 199:9	265:3,21 266:5	possibility
87:1	254:11 265:2	205:3 282:1	266:7,15 267:7	154:17
photo 364:18	308:5 358:24	291:11 299:16	267:16,21	possible 112:3
photographs	placed 124:11	314:20 355:14	331:20 332:12	114:13 225:17
364:9,10	136:18 142:23	383:4 403:10	348:4,15	372:19 393:14
photomicrogr...	181:10 217:1	417:3,8	351:18 353:8	possibly 125:9
211:7	217:13 245:15	plus 29:20	359:13 360:13	129:21 352:24
phrase 220:21	253:12 255:11	point 70:1,15	361:15 362:5	post 75:8
237:19	262:5,13 264:6	72:12 99:12	362:19 363:12	postanal 75:19

Marc Toggia, M.D.

Page 451

postoperative 129:22 155:23 216:14 404:1	preceptees 293:22	presented 28:23 52:7 87:3	priority 315:20	118:15,22
potential 180:12 272:21 273:8 280:11 362:23	preceptor 250:24 271:15 286:3 305:15 305:15 306:21 309:21	206:24 213:8 221:18 230:15	pristine 349:19 352:20	120:1 121:14 123:23 125:3
potentially 352:12	preceptorship 5:22 59:14 64:4,7 87:21	presently 275:22	privacy 18:21	126:6 129:21
powder 240:18 243:4 361:15	predetermined 226:5,14 227:9 227:17,23	prestigious 399:14	private 12:3,9 12:19 18:3	129:24 140:16 149:24 150:4
powders 241:7 242:11,22	predicated 275:19	presume 218:9	privileged 15:22	165:5,24 175:6
power 206:1 349:18	predict 402:9	pretty 66:9 186:22,24 216:15 292:14 300:24 301:10 306:24 365:23 377:12	privileges 15:21 16:18	176:4 179:6,8 179:11,14
powered 352:10 398:16	predictable 174:16	prevalence 131:23 132:1 358:13	probably 13:14 19:10 21:21 28:5 29:20,22 65:13,20 71:11 74:20 86:9 89:10 95:4 116:19 117:18 118:10 124:5 161:23 182:4 183:16 185:12 186:3 215:21 216:19 218:11 240:7 243:21 244:6,7 253:16 268:13 293:1 293:20 295:16 295:22 296:3 300:14,23 308:8 409:2	180:16 182:1 183:19,22 185:10 207:14 209:1 212:13 215:14,15,23 216:10,13,13 216:19 217:16 217:18,20 219:1 224:3,4 224:8 251:7 254:15 264:19 267:13,18 268:1,4,6,8 272:20 273:7 275:1,3,4,21 280:9 286:9 287:2 290:3 292:9 293:11 303:20,23
powerpoint 52:24 53:1 301:14,16,23	prefer 225:14	prevent 171:10 367:3	problem 111:7 152:9 156:18 210:9 236:5 357:7	331:22 332:5,7 336:10 337:18 344:17 357:4 369:19 371:23 379:12 381:23 382:2,7 387:1 389:16 396:13
powerpoints 52:19 301:18	preferred 301:19	previous 19:5 112:17 201:13	problems 110:10 140:5 155:20,21 162:9 164:20 184:15 206:20 342:20	procedures 16:17 63:20 64:8 65:19 76:22 80:9 107:9 114:21 115:21 117:22 118:2,4 125:7 125:22 127:9 153:14 159:14 173:9,14 174:3 177:12 178:6 181:4,17 184:5
practically 185:8 391:10	preliminary 77:16 113:17	previously 167:15 238:14 400:8	procedure 46:10 49:22 63:7,15 65:1,3,4 67:14 75:4 77:24 79:23 80:2 106:8 107:2,6 113:17,19 116:7,8,10,17 117:3,7 118:8	
practice 12:4,10 12:20,23 13:1 13:2,4,13,16 13:19 63:7 64:13 65:11 70:19 155:16 162:4 163:9 164:14 165:2,7 165:14 167:1 167:12,17,18 172:24 217:6 220:2,20 249:24 275:15 308:24 309:11 309:23 311:23 396:7,21 413:14	preparation 42:7 25:21 42:2 248:12 302:8	primarily 15:13 223:11		
practiced 77:24 79:23 374:10 381:22	preparing 28:14 29:15,19,22 302:4	primary 14:16 15:11 187:22 188:10 189:5 223:5 226:23 398:9		
practices 311:22	present 4:16 65:15 179:5 188:21 189:2 279:20 287:2 380:21	principles 76:12 275:5		
preceding 297:4	presentation 52:4 60:23 61:14 203:1,6 300:15 301:4 315:4	print 282:7 283:21 298:23 299:11 407:5		
preceptee 293:21	presentations 51:16 52:6,13 53:1,6 203:8 300:9 301:13 302:5 309:21 315:5,6 318:19	prior 21:17 28:22 41:9 62:22 63:5,17 63:20 72:16 73:20 80:14 106:11 185:24 216:12 238:4 244:11 245:10 247:4 254:3 292:5		

Marc Toggia, M.D.

Page 452

184:12 185:20	76:5 78:4	290:18 359:12	33:16 42:11	48:17 77:17
185:21,22	107:5 112:11	363:12 410:15	53:4,8 59:13	78:8,14,22
186:17 208:15	138:21 147:22	410:18,22	92:21 112:9	79:7 137:5
212:11 213:10	162:16 220:17	411:8	152:19 158:5	203:7 208:20
217:5,22	239:21 242:23	prolific 405:17	158:14 159:7,9	209:10,14,16
218:19,20	242:24 271:23	proliferate 74:10,11	216:12 221:12	213:14,17
223:12 263:8	280:7 292:6	74:13,15 75:3	248:3 280:8	214:22 219:16
264:1 266:2	338:18	75:4 307:20,24	303:14 309:22	231:10 233:23
275:2,6,12,14	production 8:10	308:4,11,15	315:1 358:6	234:14 235:10
276:8 286:16	159:3	311:1 338:19	provided 22:19	244:3 305:16
287:21 311:1	products 1:4	338:23,24	31:4,15,21	355:15 399:12
313:18 333:20	20:15 51:11,13	prompt 138:16	32:2,6,19	405:11 406:7
344:14 365:23	52:21 54:3	pronounce	37:12 74:2	406:21 407:11
374:9 375:8	58:14,15 64:16	375:24	101:6,22	414:2
377:1 388:6,9	65:17,23 69:7	proof 75:7	106:14 159:11	publishing
389:6,7	69:8,10,14,23	proper 241:9	161:21,24	399:22
process 143:8	72:5 73:9,22	325:19 327:5	191:11 219:24	pubovaginal
409:2	74:3,5,8,10	344:23 379:23	228:13 239:12	121:13 214:9
proctor 292:16	75:24 80:4	properly 135:5	272:15 277:12	215:15 339:24
293:6 294:10	240:24 242:17	135:7 256:24	280:17 304:6	342:21 343:2
294:11 295:3	307:13 338:12	properties	315:14 320:10	343:15,23
proctored	378:20	245:19 247:9	323:24 324:3	375:8 389:9,22
294:19,22	professional	251:4 252:24	332:1 339:21	390:1
297:10,12	87:9 94:6	350:12	355:24 366:21	pull 67:12
proctoring	273:5 309:2	property 17:3	provider 163:6	167:24 228:23
293:2 294:17	319:11 372:19	284:10,21	169:5	254:19,21
proctorship	professor 11:18	285:9	providing	pulling 90:19
5:21 6:10	11:23,23	proportion	236:13	pure 105:18
87:20 108:18	profile 179:5	175:5	provocative	145:11,13
produce 133:8	program 62:17	propounded	390:24	purpose 42:6,17
162:2 164:12	280:19	419:5	public 3:20	46:6 48:12,20
201:6	project 304:21	prose 26:18	302:1 317:12	50:18,22 173:7
produced 6:16	projections	prosimatm 7:9	317:15,16	198:9 214:6
6:18 102:8	105:9	75:2 303:15,19	419:14	228:18 322:22
103:7 158:9,24	projects 297:22	304:3,6,11,19	publication	412:23
279:10 281:15	297:23	304:24 314:11	41:10 133:9	purposes 230:13
283:20 298:24	prolapse 51:18	prospective	221:21 231:20	410:3
299:5	53:15 55:3	36:24 332:18	306:6,10 378:3	pursuant 3:12
produces 205:22	74:5 174:11,20	344:21 355:17	407:13,21	5:13,14 20:22
producing 158:7	263:9 308:16	355:21	publications	20:23
product 31:1	315:10 324:13	protected 365:5	70:17,20	pursue 97:16
66:2 68:20	386:21,24	366:22	317:21 407:15	put 22:10 32:11
70:9,11 71:20	387:1	protective	publish 316:15	77:14 282:24
72:11,14,19,22	prolene 117:19	254:10,12	318:10	288:10 322:20
73:16,20 74:24	117:21 118:3,5	proven 377:6	published 23:15	337:20 340:17
74:24 75:1,2,5	118:9 123:24	378:17	24:7 28:22	363:22,23
75:11,14,19	146:5,10	provide 31:2,9	37:5 41:12,14	364:11 383:23

Marc Toggia, M.D.

Page 453

391:4 407:5 puts 76:10 putting 42:13 90:8 149:18 158:24 236:12 pypcznski 6:6 7:12 99:22 100:7 320:3 pyramid 7:14 207:22 325:19 326:20 347:12 pyramids 326:9 327:1	151:13 154:12 158:16 159:10 160:18,21 161:4,6,15 163:22 164:11 164:16 166:21 167:5,7 171:6 171:8,10,12 172:5,8 175:14 176:11 177:1,2 179:12 182:14 182:16,22 186:13 191:22 192:3,6 193:19 193:21 194:2 196:13,14 197:12 201:10 201:11,13,22 203:17 205:3 209:7 232:8 234:8 235:20 236:8 239:2 246:2 268:20 270:13 274:17 280:22 281:2 285:23 308:4 322:19 327:8 336:2 344:24 345:24 346:1 351:15 352:1 354:23 364:17 368:11 369:20 395:14 397:2 400:14 403:9 404:9 407:10 410:20,21 414:8 questioned 110:7 questioning 129:2 346:4 questions 39:24 53:22 54:11 73:6 86:1 95:2 95:5 109:10,17 142:3 151:16 196:22 219:8	220:9 225:11 245:7 277:5 281:21 291:8 291:23 296:17 321:5 322:8,10 330:14,20 331:4 335:8,20 339:23 353:3,6 359:23 360:11 361:4 363:18 367:6 369:23 372:15 392:6,8 415:2,3 419:4 quick 215:7 quicker 160:23 quickly 119:4 319:20 quite 134:17 207:11 391:13 399:4 quote 288:4 384:20	70:22 117:18 215:22 253:4,4 263:13 298:7 386:12 389:3 ranges 182:4 rare 377:17 rarely 156:10 174:5 rate 121:14 123:18 127:21 127:23 130:16 130:19 156:21 156:24 158:3 161:16 163:11 181:6 225:12 287:12 334:13 337:23 358:7 381:7 385:22 386:7,7 rates 130:21 155:18 288:14 336:4,11,17 337:22 338:2,6 385:12 387:8 388:12,13 389:23 rating 127:22 rats 240:17 241:16 242:10 243:1,4 361:14 rattled 198:17 rct 377:7 reaction 151:8 151:21 152:2 152:13 177:23 188:12 202:6 202:10,12,14 202:19 203:18 204:14,18 205:8,16 206:8 206:16 207:3 290:19 348:7 353:4,7,23 359:22 reactions 272:5 289:3 354:3,5 reactivity	239:16 read 28:23 39:4 89:1,24 90:17 91:15,18,20 95:7 96:20 97:1,5,8,12,14 97:18,20 98:11 98:15 99:7 100:8 101:11 103:18 104:4,5 104:10,12 109:1 119:16 119:20 122:1 122:18,21 138:1,5 146:4 164:5,9 175:7 175:13,18 176:9,10,21 177:3 204:2,6 213:19 221:20 226:21 230:11 239:18 240:15 282:2,6,9 283:22 290:10 299:14,17,18 299:18,23 303:18 346:14 355:1 389:10 393:7 394:5,9 394:11 395:9 397:3,17 404:18 405:1,3 406:3,5,6 409:15 412:2 417:3 419:3 readily 66:21 reading 92:3 133:5 176:22 176:23 177:5 221:20 251:16 251:18 273:9 284:1 387:19 387:23 396:5 396:17 403:7 403:11 reads 91:22 ready 201:21
--	---	---	--	--

Marc Toggia, M.D.

Page 454

reagent 409:22	52:16 62:16	78:18 82:21	276:16,19	109:19 168:1
real 215:7	63:8 72:24	83:17 111:24	277:1 283:5,8	203:10 370:17
realized 346:7	80:18,18 81:4	112:4 123:20	283:11,14,17	371:6 381:10
really 55:19	82:16 83:11,12	133:18 271:20	291:10,13,17	referring 15:14
56:2 63:9	84:21 94:1	272:9 309:15	291:20 321:15	33:13 34:6
84:22 116:22	111:22 120:3	371:16 372:4	321:17 322:2	38:15 62:6,9
124:9,22	292:5,15 293:2	recommend	368:21,24	72:7 89:9
126:22 146:20	293:5 294:6	370:23 378:16	369:4,7 376:20	94:11 100:17
150:4 192:24	295:11 300:12	recommendat...	383:3,7,18,21	102:1 105:14
205:19 206:16	302:9,24 304:9	320:14	402:14 403:3,5	111:18 122:7
211:2 218:23	320:9 329:9	recommendat...	407:6 415:6	130:6 145:8
218:24 224:12	330:16 334:15	106:11 213:5	416:6	168:6 187:19
247:15 288:8	338:13,16,17	376:10 377:16	records 25:5	189:9 232:23
304:10 313:8	338:21 339:3	379:2,3 398:5	66:15,17 67:3	233:15 257:23
313:21 317:1	339:10,16	recommended	67:5,8,9,10,17	267:2 303:2
324:6,7 325:7	346:4 355:3	397:14	157:7 158:8,13	313:1 319:8
359:1 362:4,9	361:5,6,16	recommends	162:1,3 164:11	332:14 340:13
362:24 375:5	363:8,9 364:15	377:6 389:24	164:14 296:21	401:2 414:23
realm 19:20	367:9 381:13	reconstructive	297:8	refers 109:15
realtime 3:19	406:24	11:1 203:14	recovery 80:5	235:4 332:17
416:11	recategorized	222:7 264:21	rectus 267:11	refreshments
reason 20:4	411:20,22	record 9:11,23	recurrent 189:5	315:2,15
28:17 42:17,20	receipt 417:17	10:18 24:5	reestablish	regard 37:16
43:6,22 52:1	receive 12:9	25:8,11,15,18	140:17	38:11 72:2
77:22 86:12	156:22 158:4	32:9 34:21	refer 44:15	121:1 123:17
108:2,5 110:23	250:14,17	45:2,16 67:15	75:19 117:12	136:8 173:11
111:14 180:20	299:24	85:13,22 98:16	118:17 169:19	185:24 253:8
306:16 347:21	received 63:21	119:13,21	186:15 231:17	315:15 316:1
356:6 357:1,17	227:8 296:22	120:9,13,17,20	241:22 257:24	351:14 372:19
417:5 418:3	311:22 315:17	121:17 123:5,8	325:3	375:14 378:11
reasonable	recess 85:16	123:12,15	reference	regarded 374:2
84:19 101:24	150:16 244:22	136:5 137:15	106:15 121:1	regarding 30:10
213:8 215:2,4	271:1 276:21	137:17,21,24	124:14,19	34:22 42:14
410:12	321:20	138:6 150:13	125:18 236:14	43:20 60:9
reasonably	recognitions	150:22 159:1	320:16 332:9	73:7 100:13
36:15 327:8	315:17	159:18 162:7	referenced	103:13 109:10
360:18 368:12	recognize	164:10,17	359:5 381:5	112:11 195:3
reasons 14:20	299:19	168:10,12,16	references 240:9	230:18 239:15
139:16 345:4	recognized 46:9	168:19 194:6	331:24 332:2	293:1 316:4,19
374:22	49:17	194:10,14,17	333:23 372:12	404:19
reassure 110:11	recognizing	199:7,9,11,15	referencing	regardless 109:8
reassured	301:24 324:6	199:18 200:13	57:21 121:8	163:8 221:11
344:11	recollected	201:14,16,18	373:4	260:6
reassuring	298:9	244:17,19	referral 13:3	region 184:3
135:11	recollection	245:4 270:22	104:14 186:5	215:21
reath 3:14	52:17 60:22	271:5 274:3,5	312:22	regional 286:11
recall 26:22	61:1 75:22	274:8,11	referred 13:9	329:2

Marc Toggia, M.D.

Page 455

registration 134:22	238:6 241:14 243:7 277:11	360:16 368:11 369:14 373:11	removed 181:20 308:12 350:17	395:1
registries 152:4	278:1 409:24	374:2 379:24	removing 183:11	reported 131:18
registry 7:9 37:1 131:10 140:4 169:20 191:3 303:15,24 304:6 314:11 323:12	relates 1:6 114:16 144:14 178:8 200:1 203:10 248:4 385:2	384:9 391:23 reliably 358:20 364:20 373:2	render 260:12 reoperation 386:24 387:15	132:2,7,10,12 132:14,16 133:4,15 362:15 393:19 395:2 397:15 399:12 400:4,8 404:3
regular 155:19 165:18 279:22	relating 51:16 52:13,20 53:9 303:14	24:8 31:12 33:24 34:6 195:19	rep 71:11 81:5 82:13,17,23 83:5,15,17,24 84:9 86:4 87:8 90:9 93:19,20 93:21	reporter 3:19 9:24 97:17 98:15 119:20 138:5 164:9 416:11,21
regularly 337:13	relationship 15:6 43:21 60:7 72:3 81:3 84:11,20 87:8 87:11 246:2 306:13 313:17 314:3 317:8 318:24 319:11	reliant 332:23 relied 363:11 368:9 392:18 402:4	repair 1:4 7:17 382:21	reporting 207:13 397:14 398:1,21 399:5 400:18 401:5 403:16 404:12 404:20 407:15
regulatory 238:22,24 239:5 408:24 409:2	relationships 61:7 84:24 317:2	relies 335:4 relooked 271:23 rely 72:3 106:23 146:15 162:2 164:12 178:18 179:3 248:2 269:7 333:24 340:24	repeat 45:23 161:5 172:16 274:22 403:10	reports 23:17 34:18 38:14 40:5 230:23 240:21 278:23 324:14 364:7 367:11
reimburse 300:4 307:3	relative 181:3 221:4 261:17	relying 399:1	rephrase 77:15 161:5 182:19 205:2	represent 10:11 411:7
reimbursement 215:12,18 216:3,10 237:13 294:13	relax 105:11	remains 255:12 262:14	replace 263:16 replied 320:20	representative 61:19 356:11
reintervene 185:7	relatively 215:2 219:9	remember 58:23 70:9 74:17 81:10,22 82:7 83:4,13 83:15 84:6 109:19 110:2 151:4 183:21 280:24 292:1 301:20 302:4 303:13 304:4 304:19,23 309:7 312:8,14 320:18,24 331:3 354:23	reply 86:18 report 5:16 23:21 24:7 25:21 26:3,20 27:7 28:14 29:15,19,24 31:13 33:17 34:8 35:8,13 48:21 57:21 58:16 118:18 183:24 186:7 187:3 234:24 241:23 272:18 273:10 277:11 278:1,5 310:21 318:10 325:17 328:23 334:5 337:21 340:6 346:8,10 354:10,17 359:12 361:8 364:11 365:14 385:7 387:6,20	represented 318:19 representing 4:7 4:13 represents 106:8 352:17
reintervention 174:6 180:20 329:1 386:18	relevance 33:21 408:4	reminding 308:20	rephrase 77:15 161:5 182:19 205:2	reproduction 416:19
reissue 280:15	relevant 17:22 18:23 23:14 32:20 36:11 37:6,16,23 38:21 53:17 146:21 153:11 242:3,13 250:3 250:3 255:23 256:4 260:18 326:5 333:15 360:15 361:20 365:3 368:15 369:14	removal 172:12 172:19,20 183:14,15 357:8	report 5:16 23:21 24:7 25:21 26:3,20 27:7 28:14 29:15,19,24 31:13 33:17 34:8 35:8,13 48:21 57:21 58:16 118:18 183:24 186:7 187:3 234:24 241:23 272:18 273:10 277:11 278:1,5 310:21 318:10 325:17 328:23 334:5 337:21 340:6 346:8,10 354:10,17 359:12 361:8 364:11 365:14 385:7 387:6,20	representing 4:7 4:13 represents 106:8 352:17
rejection 188:6 188:14 189:13 189:13 190:5 190:12,17 199:1	releas 105:11	removal 172:12 172:19,20 183:14,15 357:8	report 5:16 23:21 24:7 25:21 26:3,20 27:7 28:14 29:15,19,24 31:13 33:17 34:8 35:8,13 48:21 57:21 58:16 118:18 183:24 186:7 187:3 234:24 241:23 272:18 273:10 277:11 278:1,5 310:21 318:10 325:17 328:23 334:5 337:21 340:6 346:8,10 354:10,17 359:12 361:8 364:11 365:14 385:7 387:6,20	representing 4:7 4:13 represents 106:8 352:17
relate 20:14 22:12 29:3 30:23 35:3 39:12 224:1 329:18 345:10	releas 105:11	removal 172:12 172:19,20 183:14,15 357:8	report 5:16 23:21 24:7 25:21 26:3,20 27:7 28:14 29:15,19,24 31:13 33:17 34:8 35:8,13 48:21 57:21 58:16 118:18 183:24 186:7 187:3 234:24 241:23 272:18 273:10 277:11 278:1,5 310:21 318:10 325:17 328:23 334:5 337:21 340:6 346:8,10 354:10,17 359:12 361:8 364:11 365:14 385:7 387:6,20	representing 4:7 4:13 represents 106:8 352:17
related 35:2 48:22 93:11 94:2,9 110:9 155:12 184:4 184:11,20 186:17 205:21 214:13 223:2 223:12 224:9	releas 105:11	removal 172:12 172:19,20 183:14,15 357:8	report 5:16 23:21 24:7 25:21 26:3,20 27:7 28:14 29:15,19,24 31:13 33:17 34:8 35:8,13 48:21 57:21 58:16 118:18 183:24 186:7 187:3 234:24 241:23 272:18 273:10 277:11 278:1,5 310:21 318:10 325:17 328:23 334:5 337:21 340:6 346:8,10 354:10,17 359:12 361:8 364:11 365:14 385:7 387:6,20	representing 4:7 4:13 represents 106:8 352:17

Marc Toggia, M.D.

Page 456

110:17 193:24 286:22 413:21 requested 158:2 161:22 requests 5:14 20:23 require 172:12 172:20 175:4,5 180:20 required 173:9 174:5 184:14 336:15 requiring 167:19 387:8 requisition 6:21 296:10 research 12:1 23:4,15 37:19 38:22 141:15 144:4 310:9 397:8 398:14 398:23 408:6 researched 407:24 researchers 373:16 reserve 217:9 reserved 9:7 348:8 residency 218:8 residents 217:24 218:4,12,22 318:14 resin 144:22 145:5 resolved 14:14 173:17,19 respect 201:8 respected 336:22 respectful 199:21 200:19 402:19 respond 206:12 348:19 responded 372:1	response 91:23 92:11 188:11 189:6 190:6 193:11 196:4 197:10,14,19 198:14,19 199:1,3 203:12 211:17 289:9,9 289:21 353:13 responsibility 318:9 responsible 15:13 219:21 responsive 113:4,9 136:7 161:10 172:4,7 rest 277:5 restate 136:20 restaurant 302:1 restrict 13:17 restroom 128:20 result 181:12 208:14,24 264:1 274:16 289:10 290:5 312:10 315:18 349:1 354:6 390:8 resulted 314:17 390:12 results 176:1 225:22,23 226:5,14,18,19 227:3,5,9,22 231:7,10,22 235:10,21 237:14,17,20 237:23 253:15 303:24 304:1 retain 30:22 retention 256:7 reticulocytes 258:17 retreatment 404:6 retropubic	64:13,15,19 65:2,3,11,14 72:10 77:5 129:11 131:19 155:6,13 178:9 181:7 182:15 183:10,22 267:2 307:22 332:15 334:11 334:20 335:1 336:4,18 337:24 338:7 341:6 342:4,8 360:17 366:15 375:12,18 379:6,11 381:16 384:18 389:19 394:19 395:17,22 retrospective 355:21 return 130:10 162:14 163:5 168:3 169:5,9 343:3,15 344:1 417:15 retzius 267:11 reuters 329:22 review 7:22 30:1 31:3 40:23 117:13 121:4,6 179:4 222:19 271:13 323:19 325:20 327:12 328:18 333:5 333:13 334:6 334:16 340:19 341:11,12 342:13,17,17 342:19 343:13 344:15 373:3,7 374:16 383:14 384:2,6,10,13 384:15 392:16 393:23 396:16 398:24 401:24 reviewed 24:16	28:19,20 33:23 34:3 35:3 37:4 38:7,14 41:3,7 41:9,16 191:10 223:2,11 226:3 271:8 279:19 323:4 330:7 340:24 376:14 380:1 381:2 reviewing 28:21 70:19 304:1 342:3,6 reviews 36:24 198:1 323:8 325:4 328:14 330:12 332:24 335:5,12 359:3 376:18 389:18 revise 183:18 185:12 revision 181:21 183:15 184:3 184:10,15 revisions 185:19 rewarded 315:13 rice 4:3 richard 10:19 riddle 16:4,10 right 14:24 29:9 30:7 32:23 40:2 62:13 64:11 74:22 83:11 92:21 96:1 97:5 119:2,10 126:13 127:18 128:5,18 133:2 139:18 141:12 150:7 151:12 167:24 177:7 194:22 204:12 206:17 211:23 219:22 224:18 233:24 234:3 244:8 246:7 272:22 298:3	323:11 330:24 340:15 349:11 364:17 372:7 384:21,22 393:6 396:22 rigorous 324:24 risk 105:5 106:17,21 107:17 114:13 114:15,16 115:4,5,8 116:19 121:10 121:21 122:3 123:21 124:2 125:20 130:9 130:13,15,17 180:6,13,18,21 220:22 221:2,6 256:7 261:8,17 261:19 262:19 269:21 273:20 275:8,9,9,11 276:4 362:9 387:13 388:21 388:22 risks 44:13 46:5 46:23 48:24 50:24 107:10 112:12,16,24 114:5,11,12,22 115:3,11 116:12,15,23 125:4,5,7 126:6 129:12 181:1 272:21 273:8,18 274:15,16 275:11,23 276:6 280:11 386:11 388:17 robert 7:18 382:22 robust 377:7 379:4 robustly 398:15 role 70:19,20 219:3 297:21
---	--	---	---	---

Marc Toggia, M.D.

Page 457

341:20,23 rolling 255:7 room 17:10 22:15 105:4 295:4 343:4,16 344:2 350:16 rope 254:8 262:7 roped 262:10 roping 254:1 256:6 257:1,14 260:11 261:7 262:17 269:1 269:19 363:18 rosenzweig 34:14,17 38:16 354:12 rosenzweigs 354:7 364:11 rough 290:6 roughly 70:11 234:11 235:1 281:5 292:11 386:11 388:10 routes 393:15 routinely 60:14 135:4 210:13 210:16 royalty 316:16 rule 5:14,15 20:22,23 152:18	77:13 78:3,9 78:13,14 79:6 79:10 80:4 105:19 146:23 147:3,4 152:8 179:5 195:3,8 195:13 197:16 220:11 221:1 229:20 238:6,9 239:4,8,15 279:5 322:16 325:9,21 328:20,21,24 331:6 332:8,13 339:6 341:4 344:7,16 347:18 353:22 359:6 360:12 364:21 369:19 373:13 374:17 377:3 378:11 414:20 sake 183:21 salary 316:24 sales 71:2,7,11 71:15,17,21 81:3,4,11 82:13,17 83:5 83:15,24 84:9 84:11,12 85:2 86:1,4,13 87:8 87:12 88:11 90:9 93:19,20 93:21 312:10 samples 349:8 sarcoma 241:5 241:14,21 243:15 268:16 361:4 362:9,16 363:14 sarcomas 240:19 361:14 satisfaction 237:12 satisfied 270:8 saw 74:8 100:14 103:14 162:8	164:19 166:10 193:13 245:8 324:11,15 336:14 349:6 350:5 367:16 371:12 389:23 saying 44:8,9 52:6 60:18 71:24 73:18 78:23 79:1,2 127:16 130:24 133:6,7 149:6 155:10 158:23 193:8 231:18 259:10 273:13 275:16 299:7 321:1 371:22 379:1 390:22 409:6 says 47:18 89:4 90:4 101:14 103:11 237:19 240:8 282:21 282:23 295:9 371:8 376:24 377:5 379:19 396:6 scale 357:22 scanning 347:4 349:17 352:10 scar 263:17,21 scarless 264:14 scarring 263:24 264:2,4,12 scenario 300:13 schedule 16:12 21:23 22:12 51:6 scheduled 157:10,23 schepleng 2:21 schimpf 340:4 340:17,18 342:12,16,24 343:12 354:18 388:19,20 389:22 402:2	402:21 403:14 schimpfs 404:19 school 11:20,21 251:24 schumpelick 7:18 382:22 science 236:9 241:12 scientific 37:3 39:6 40:17,18 41:1 42:12 70:17 76:11 80:10 131:14 325:20 344:23 373:11 378:10 379:24 scientifically 37:23 324:24 330:8 341:4 346:20 358:6 358:19 360:16 364:19 368:10 369:13 384:8 scientist 354:1 362:12 scientists 373:16 scope 18:22 186:18 248:12 score 391:16 scratch 69:4 scrubbed 89:21 se 115:17 249:3 249:5 290:10 347:1 362:5 410:18 sealing 9:4 second 25:9 121:18 156:5 174:14 180:15 241:23 284:8 284:14 340:9 secondary 404:12 secrecy 303:21 section 270:13 272:6 396:6 397:8	sedation 286:20 see 21:16,19,23 41:12 51:8 66:22 76:4 117:5,9,19 155:20,22 156:1,14 179:23 180:10 209:10 211:17 211:18 220:11 228:22 229:9 237:18 240:7,8 241:6 242:1 246:1 255:22 260:17 278:11 281:10 284:13 299:19 302:2 313:4 329:4 340:12 350:4 368:21 370:23 371:2 377:22 380:15 381:1 389:17 390:23 398:6 408:1 412:6 seeing 268:16,18 348:24 367:9 406:24 seek 175:1 178:19 270:5 376:6 seeking 179:2 seeks 333:15 seen 58:4 114:3 151:24 155:5 155:12,18 157:21 163:15 171:17 178:11 184:17 188:7 202:2 203:4 204:14 228:9 239:7 244:9 248:24 249:7 249:13 253:15 267:22 337:15 363:22 364:5,6 364:7 389:5
--	---	---	--	--

Marc Toggia, M.D.

Page 458

399:14 sees 274:20 selection 6:18 281:14 329:19 345:7 356:7 send 13:21 14:15,21 210:13,16,16 sending 102:13 312:8 sense 35:14 136:13 258:8 263:24 307:5 310:2 312:4 315:11 319:17 333:19 347:3 sent 32:9,21 100:22 101:9 102:24 103:5 103:18 109:16 278:4 sentence 40:14 91:16 95:7 96:20 97:1,13 99:7 122:18,21 176:23 187:18 284:15 286:8 396:22 sentences 239:18 240:15 separate 264:9 305:18 separately 391:14 separating 300:16 sepsis 128:12 september 27:23 28:2 378:3 sequelae 206:13 serial 119:3 series 37:20 48:17 155:24 225:10 234:24 265:8 357:13 358:16 399:4	399:13 400:5,7 400:16,18,24 401:1,5 serious 128:13 240:22 serve 30:5 341:20,21 401:22 served 317:9 serves 30:7 service 15:12 304:5 services 74:2 167:20 216:11 296:23 297:19 303:14 304:18 serving 286:2 session 60:17 set 73:17 288:2 349:16 setting 134:13 219:4 seven 119:12 132:9,22 133:7 133:15 165:3 166:12 234:16 357:2 severe 38:2 126:12,15 127:6,7,17,23 128:10 174:17 175:3 353:5 severity 126:1,7 126:10,19 127:1 sex 92:18 96:16 96:19 sexual 181:2 318:24 370:6 sgs 328:16 335:13 340:18 389:24 share 100:15 103:15 380:4,5 shears 2:6 sheath 254:10 254:12,15,18	255:8 364:13 365:6,16 366:3 366:7,12,16,21 366:22 367:3 368:4 sheathless 368:3 sheet 6:15 238:6 238:9 239:5,8 239:15 279:5 360:13,15,24 361:13 417:7,9 417:12,15 419:6 shes 89:9 93:4 shift 112:18 shocked 324:17 short 55:23 315:24 shortterm 213:9 213:10 shouldnt 146:3 225:21,24 402:16 show 47:6 57:10 137:3 142:22 168:5 173:21 191:15,18 198:16 233:14 233:19 248:19 290:17 301:14 346:3 348:3 353:12 359:5 414:9,10,11,11 414:12 showed 121:9 137:7 260:10 362:9 showing 248:20 shown 238:4,5 301:15 360:12 shows 134:16 146:10 162:13 197:9 298:1 359:12,19 shrink 154:15 shrinkage 153:12,20	258:9,10,12 shrinks 153:3 258:4 shunt 328:16 shy 244:7 sick 94:22 sicker 345:8 side 80:10,10 324:4 382:5 sidney 11:21 sign 417:8 significance 125:24 227:5 329:8 333:11 385:14 414:12 significant 72:13 131:3 140:4 175:5 196:4 197:19 211:22 258:12 294:5 312:3 353:22 386:6,6 386:7 387:13 399:4 406:20 significantly 38:17 231:10 388:23 signing 417:10 similar 38:17 42:15 115:8 213:2,11 253:19,20 267:9 328:11 356:16 375:6 388:11,18 389:5 409:24 simple 219:9 225:11 390:22 395:14 simplify 40:13 simply 49:16 55:3 75:3 86:19 164:5 278:22,22 288:7 303:17 304:1 312:19 313:12 315:14	327:21 348:11 350:20 351:6 390:9 simultaneously 63:13 317:5 single 40:14 155:11 188:3 202:2,5,8 206:15 292:23 336:12 sir 270:20 330:23 sisters 13:12 sit 67:15 69:15 78:18 79:2 site 137:6 233:3 240:19 289:8 290:5,13 sitting 27:2 124:13 situation 160:10 293:11 295:6,7 309:7 315:3 situations 391:1 six 119:14 156:8 165:3 166:12 297:6 size 55:5 sleep 287:8 slide 302:5 slides 210:19,21 sling 7:20 46:9 47:10 64:16,20 73:8 75:8,20 115:9 121:13 124:24 125:11 125:12,19 130:5,6 131:4 153:7,17,20 155:7 156:23 171:24 172:12 173:7 177:11 181:7 184:21 212:16 214:9 215:15,17,18 217:3,4,16 218:11 219:2
--	---	---	--	---

Marc Toggia, M.D.

Page 459

266:4,20,23	24:4,21 25:6	190:8,19 192:2	326:10,23	77:15 81:17
267:1,4,8,18	30:15,17,18,20	193:2,7,12,18	351:13 364:4	82:5 83:2,6
268:12 326:5	31:4,14,23	195:5 196:8,24	367:15 368:6	89:12,15 97:24
331:13 332:12	32:1,6,8,14,19	197:23 198:21	368:20 369:8	104:14 107:14
332:15 339:24	34:20 35:21	199:4 202:21	370:10 380:6	109:5 110:16
340:11 342:22	40:7 41:4	203:20 204:2,6	380:14 382:11	112:22 114:7
343:2,15	42:22 43:2	204:9,19,24	383:5,22 387:5	118:21 121:24
356:19,20	44:1,16,18	205:10 207:16	392:5 394:2	122:9,23 123:2
360:1,7 371:13	45:1,7 46:17	208:8,11 209:2	395:11 398:2	125:20 127:11
372:7,9,13	47:1 48:4 49:2	209:11,24	399:7,16 400:9	128:1 129:7
375:8,16,19	49:5 50:13	212:2 214:17	400:11 401:8	151:12 160:19
380:22 383:12	53:4,9 54:4,17	221:22 226:8	401:15 404:21	163:22 172:15
384:6 388:24	56:13,20 59:15	227:10,14,18	405:6,15	182:18 196:16
389:8,20 390:1	60:19 61:16,20	228:11,19	406:13,22	200:17 201:19
390:1 396:24	62:19,23 68:7	229:12,23	407:4,17 408:3	218:14 223:9
slingonly 174:3	76:6 80:15	230:19 231:14	410:8 411:10	226:9 227:15
177:8	85:4,9 88:5	232:14 233:16	411:15 412:4	235:17 239:3
slingplasty	90:13 91:17	234:5 235:11	413:4,15	246:1 252:5
381:9	92:14 95:10,15	235:14,22	414:16 415:3	259:13 270:7
slingrelated	95:19,22 96:3	237:6 238:1	snippets 111:19	273:11 282:3,6
173:13	96:10,14,17,24	242:7,19	snodgrass 2:13	284:16 285:23
slings 41:20	97:6,10,22	243:19 244:16	snow 4:10	302:23 305:24
44:14 45:6,22	98:4 102:3,11	245:16 246:23	soandso 372:11	311:10 321:8
46:5 47:16	103:20 104:12	247:24 248:22	societal 323:16	331:15,18
48:9,23 49:17	108:7,21 111:1	252:10,20	societies 37:6	340:16 343:18
65:7,9 115:6	111:5 112:1	255:17 256:11	society 318:18	351:20,22,23
115:19 125:16	113:3 119:12	257:7 258:5	318:20 341:13	358:8 376:22
185:13,14,15	125:1 128:17	260:2,15	341:19,22,24	387:22 400:20
186:9 212:1	128:23 136:3	261:11 262:21	sodium 239:24	402:8 407:19
217:8 333:4	139:3,9 141:18	263:18 265:22	software 409:23	414:5
343:22 363:6	143:15 146:12	269:4,23	sole 173:10	sort 14:3 36:5
374:6 381:21	147:11 148:1	272:23 273:3	solely 360:22	36:10 37:7
389:9 394:24	148:15,24	274:2,18	somebody 76:9	86:11 107:1
slower 273:12	149:9,19	276:13 277:12	89:21 102:14	130:15 181:23
small 56:4 105:7	151:16 152:15	277:18 278:3	140:12 157:18	308:7 312:14
153:9 180:18	153:21 154:2	282:11 285:1	225:8 336:21	314:21 317:3
283:21 349:21	154:19,23	285:19 287:16	336:22 371:8	333:18 337:1
smaller 267:20	158:6,22	289:23 298:4	406:19	351:9 359:18
smallness 282:7	159:21 161:7	298:19 299:2,8	somewhat	373:22 377:20
smear 15:11	162:17 163:17	299:12 303:9	251:22 254:19	377:20 382:4
smears 14:2	163:23 164:2,6	304:7 305:21	275:5 388:18	386:14 389:2
snacks 315:1,14	165:19 167:2,6	309:24 311:4	388:18	390:2 412:6
snell 4:10,13 5:6	167:13 170:2	311:16 316:7	sorry 33:11 34:9	sought 73:20
14:6 17:22	172:6,15	317:23 318:5	42:13 43:1	172:1
18:2,10,19	176:13 177:19	319:2,6,13	51:21,23,24	sound 76:11
21:6,9 22:18	178:1 182:9,13	321:14 322:6	52:11 53:11,16	272:22 298:3
22:21 23:1	185:2 187:6	325:13 326:7	68:11 69:1	300:22 301:4

Marc Toggia, M.D.

Page 460

410:5	341:10 377:10	210:14,17	138:13	184:7,8 206:14
sounds 40:2	388:10	350:5	stands 376:1	213:8,20,23
62:14 64:1	speaks 159:18	speculate	403:19,22	214:1,4,16
89:20 301:1	198:13 231:22	102:12,17	staring 151:12	215:2 275:24
410:12	237:14 275:24	407:7	start 35:19,20	276:2 284:24
source 71:8	353:21 365:12	speculation	69:3 70:6	286:4,6 289:12
186:5 207:2	390:18 396:23	102:4 111:2	193:15 327:13	289:15 291:6
sources 316:5	specialty 10:23	112:2 148:17	352:11	313:5 330:15
374:3	12:23 37:6	149:20 406:14	started 91:1	331:5,11
south 4:5	specific 15:9	spell 81:18	129:1,6 253:2	332:23 333:24
southeast	23:24 39:24	spelling 26:17	271:10 277:4	335:3 355:9
223:23	48:14 56:8	spend 28:13	329:10	361:18 370:1
southern 1:1	57:23 113:21	38:19 179:1	starting 372:23	378:9,15
9:20	113:22 117:16	201:24 224:19	starts 175:22	379:23 381:4
space 203:9	117:16 127:12	sphere 222:1	331:19	382:13
267:10,12	137:7 144:20	223:13 224:21	state 3:20 10:17	statements 37:5
417:6	159:17 160:13	229:18	53:20,22 56:7	41:8 42:15
spacer 288:7	180:5 215:14	spin 104:23	97:12 136:23	200:10 323:16
span 28:20	216:18,20	split 29:22	154:3 165:11	333:24 335:11
spanish 282:5	233:14 236:12	spoke 94:16	262:9 313:23	stateofmind
284:2	257:12 276:5,7	105:19 259:1	313:24 322:14	102:6
sparse 404:7	290:2 365:9	spoken 253:17	348:18 352:20	states 1:1 100:18
speak 13:4 36:6	400:16 408:15	sponsored 60:17	387:7 417:5	134:24 198:18
130:1 162:20	410:3	62:2,17	stated 42:10	204:16 205:6
173:3,12	specifically	spreadsheet	47:9,14 58:17	206:7 231:7
178:10 181:1	30:22 33:13	6:22 297:24	106:9 153:16	284:9 289:6
190:1 193:16	38:15 39:12,14	298:11,16	165:9 179:16	290:17 351:17
196:7,9 197:18	49:16 52:5	spreadsheets	198:4,4,5	395:9 396:8
198:1 207:8	56:6 78:5	413:19,22	207:5 252:7	397:20 403:14
230:14 256:3	130:7 139:11	sprout 1:9	262:13 272:19	408:14
261:3 269:16	141:4,10 152:8	square 3:15	292:4 323:5	static 255:7
272:10 294:3,4	160:9 181:3	stability 140:17	348:10 351:1	stating 58:5
310:14 313:20	238:22 259:1	239:15	353:10 362:1	90:10 260:1
354:2 358:20	267:1 301:21	stabilize 267:21	362:18 365:4	status 17:13
359:2 369:18	312:11 334:20	stabilizes 268:9	408:17	stay 372:18
373:10	343:5,19 344:2	stack 254:22	statement 15:2	385:3
speaking 23:12	346:24 347:12	stand 178:1	38:12 39:2	stenographic
23:13 143:22	348:18 374:7	standalone	40:16,19,21,22	9:23
153:24 158:17	374:14 375:19	177:11 218:18	41:19 42:7,9	stepbystep
160:6 174:22	379:1 394:15	standard 46:10	42:11,18 43:13	280:8
175:11 183:21	394:17 401:5	49:18 380:21	44:12 45:5,13	steps 251:7
185:8 193:18	specificity 172:3	381:17 382:17	45:21 46:3,7	257:12
206:19 220:16	272:3,4	404:14	48:20 49:13,14	stevens 2:11
250:2,6 263:2	specifics 83:7	standardized	49:21 50:3,4	stick 321:12
276:3 290:1	specimen	79:13 398:17	50:12,19 51:1	sticker 282:19
300:19,21	350:22	standpoint	51:3 58:12	282:20,22
305:3 328:20	specimens	137:11 138:9	161:8 171:21	stipend 300:20

Marc Toggia, M.D.

Page 461

stipulate 237:11	265:20 363:24	233:23 234:13	333:7 334:4	365:21 397:2
stipulated 9:2	stretches 245:14	240:21 241:3	339:9 342:14	subset 217:9
stipulations	stretching 246:8	241:19 243:6	346:17,19,19	subspecialty
8:15	strictly 12:19	270:3 288:16	346:24 347:2	12:24 13:2,16
stop 153:23	168:2,8	290:17 323:13	347:21 348:2	14:22 29:3
197:23 276:9	strike 48:5	324:5,5,14	353:1 354:24	144:14 251:22
276:14 308:10	103:21 172:6	325:2,15 330:6	355:4,17,19	substance 419:6
stopped 108:3	238:2 268:21	334:18 343:20	356:1,4,6	substantial
stopping 128:19	327:5 328:4	344:20,21	357:3,11,24	296:6 390:11
straddle 221:2	335:9 342:14	346:1 347:10	358:1,2,4,5,6	substantiated
straight 283:9	355:7 373:6	353:17 355:20	358:15 367:19	362:24
streets 3:15	385:5	355:22 362:7	373:6,10 381:7	subtitle 175:22
stress 7:21 36:16	strip 55:22	369:11,11	393:2 397:5	suburban 16:1
39:15 47:11	strong 239:21	377:15,21	403:13	155:17
49:19 51:19	strongly 306:24	386:5 387:10	stuff 18:13 23:4	suburethral
52:20 53:15	struck 38:12	387:12 392:20	71:10 101:17	380:22
80:1 112:19,20	structural 134:8	392:22 395:6	104:22 106:24	success 221:9
144:3 153:8	136:1,5 259:4	397:1 414:22	154:8 207:10	225:12,13
155:3 156:9	structure	414:24	226:15 238:24	287:12 288:14
165:15 173:8	136:14	study 40:17 77:5	247:14 278:6	succinctly
174:15 183:23	strung 94:3	77:8 79:9,15	278:16 300:17	188:18
191:1 212:5,8	stubs 296:24	120:7,24 121:5	sub 131:17	suffer 406:16
212:12,20	studied 259:21	134:15 137:4	subcutaneous	suffers 370:20
214:10 241:10	329:1 331:21	137:13 138:12	240:18 267:12	sufficient 19:1
255:2 315:8	332:5 378:21	138:19 163:1,3	subject 5:20 6:6	28:4 194:24
322:18,23	379:8,12	168:1 169:13	6:9 7:9,12	226:24
325:11,22	studies 23:14	169:14,16	87:19 99:22	sufu 45:21 48:21
327:9 334:12	36:20 37:19,21	170:5 173:12	101:12,17	198:6 331:5,11
335:11 344:9	38:7,18,21,22	174:1,24 175:8	102:15 108:17	332:22 333:23
345:2,19	38:23 40:6	175:13,17	144:4 189:22	335:3 382:3
346:22 347:9	48:22 77:14	176:1 192:18	291:2 314:10	suggest 134:19
347:13 359:14	78:15 117:13	195:23 196:1	320:4 417:10	143:2,24
360:19 361:21	120:11 131:10	196:10,19,22	subjective	240:21 386:5
363:15 364:24	131:12 134:18	206:2 220:14	389:20,23	387:16
366:9,18	134:22 136:16	221:11,19	390:14,18	suggested
368:16 369:15	136:23 137:2	226:3,22,23	391:8,20	388:20
370:20 371:7	138:17,24	227:24 231:13	398:18	suggesting
378:12 379:8	139:24 140:18	232:13 233:3	subjectively	102:8 345:21
380:20 381:17	142:21 143:2	233:15,20	391:12	suggestion
382:15 383:13	146:10,20	234:11 235:5,8	submission	91:14 99:2
385:10,17	178:21 179:3	236:14,23	306:9	399:2
390:15,24	197:17,18	237:3,5,10,11	submissions	suggests 116:22
stresses 284:11	219:7,12 220:1	237:14,19	223:19	133:24 140:5
284:22 285:10	220:11,24	302:19,24	subscribed	190:23
stretch 252:16	224:17,22	303:16 304:3	419:10	sui 175:2 273:18
265:13	225:7 230:17	305:5,11 306:7	subsequent	380:22
stretched	232:21,24	306:11 328:16	130:4 156:7	suitability 339:6

Marc Toggia, M.D.

Page 462

suitable 368:12	403:2	surprise 243:17	188:20 189:1	58:2 74:22
suite 3:15 4:11	surface 55:18	243:22	404:1,3	80:7 85:6
11:11	56:3 350:21	surprised 48:13	syndrome 155:5	128:17 137:6
suited 322:21	414:11	321:2	155:12 207:1	150:10 157:20
summarize	surgeon 89:10	surprising	syndromes	166:18 172:21
386:15	100:16 103:16	268:15	154:18	205:21 216:22
summary 40:22	168:4 181:10	surrounding	synonym 359:18	270:9,18 331:9
42:11 343:11	247:14 260:23	205:16 366:23	synthesis 397:12	333:17 337:5
343:13 393:1,5	274:24 275:19	suspect 95:3	synthetic 64:20	351:24 354:20
sunshine 317:13	287:21 345:11	216:2,6 408:21	115:15 124:23	402:16 410:10
superior 332:8	354:1	suspending	125:15 131:4	413:8
supervision	surgeons 64:8,9	140:12	174:18 175:1	taken 3:12 49:15
416:21	273:19,19	suspension	214:12,14	85:17 150:17
support 8:2	339:4 341:14	124:10 266:6	215:17 266:23	244:23 257:13
57:14 110:1	403:23	266:21,22	266:24 374:6	271:2 276:22
146:22 373:7	surgeries 16:5,9	389:7	381:20	311:16 321:21
387:12	16:22,23 17:2	suspensions	system 1:4 16:1	takes 200:8
supporting 78:2	112:15 172:13	265:1	69:20 169:18	talk 58:13
supraphysiol...	172:21	suspensions	170:17,19	113:13,16
253:4,21	surgery 7:12,17	202:11	171:17 297:13	129:19 130:14
sure 21:13 29:12	11:2 16:19	suture 115:16	330:1 376:12	180:12 194:7
34:5 35:15	17:5 75:20	117:2,19 118:3	404:16	221:5,6 246:12
36:8 42:4	146:8 157:8	118:6,14 120:1	systematic	251:4 279:15
44:17 53:12	175:3 181:21	121:2 122:3,10	36:23 40:23	288:1 303:23
54:21 60:6,16	182:7 186:2	122:11,15,22	117:13 179:4	315:6,9 328:24
61:10 64:10	203:14 216:11	123:18,21	198:1 323:8,19	334:4 337:1
68:13 86:7	220:20 221:1	124:3,7 146:10	325:4 327:12	365:15
92:7 94:15,20	222:7 264:14	264:6,17 265:3	328:14,18	talked 114:11
114:7,10	266:16 273:18	265:3,5,7,19	330:12 335:4	122:21 219:6
117:14 126:3	275:23 276:4	267:3,7 268:3	335:12 340:18	302:18 338:9
127:3 142:20	320:4 371:9	290:5 411:8,24	341:11,12	352:15 361:14
145:7 157:9	380:22 382:21	412:11,12	342:13,17,19	371:21
186:24 196:19	387:8 388:15	sutures 117:21	343:13 359:3	talking 45:3
203:23 214:3	surgical 16:17	117:23 118:5	376:18 384:13	53:21 56:5
221:14 228:19	16:19,20 17:2	121:11 122:5	384:14 389:18	63:2 68:8
232:19 240:16	107:9 165:24	123:24 264:23	systemic 188:11	121:20 122:2
263:24 270:16	173:16 174:5	266:5,8,12	189:6	127:21,23
280:13 292:14	175:4,6 179:10	410:15,18,22	systems 170:9	129:3 135:15
296:5 298:13	184:3,10,15,19	411:6,8	170:11,13	135:17,21
302:7 306:5	185:19 186:1	swear 10:1	323:14 329:3,8	141:5,7,8
307:7,21	264:1 275:12	switch 372:20		147:1 169:22
311:24 315:23	328:24 360:5	switched 68:17	T	177:9 193:16
333:14 335:24	376:9 388:4,5	sworn 10:4	table 171:13	208:20 211:13
339:2 356:10	405:13,22	416:5 419:10	176:11 254:22	219:10 224:20
358:10 365:18	406:10	symptom	342:24 343:5	232:20 237:2
370:13 378:18	surgically	180:13 390:16	take 13:5 15:3,8	238:21 246:10
383:5 400:10	183:18	symptoms	24:14,19 58:1	257:17 263:21

Marc Toggia, M.D.

Page 463

276:6 292:10	76:23 360:5	236:18	375:23 416:7	133:17 134:11
295:3 316:6,8	388:17	tells 173:22,22	testing 189:16	134:12 135:6
329:7 394:14	technologies	ten 19:12 62:3	190:2 240:6	135:14 139:10
394:16,17	1:23 9:14	112:17 131:10	252:7,23 253:1	145:10 155:14
400:6,15,17,23	telephone 225:8	131:12 165:4	257:23,24	158:17 160:5
405:18	tell 18:7 19:9	167:7 171:20	349:7 363:19	161:11,13
talks 253:17	22:7 24:15	191:5 234:17	363:22 364:6,8	163:16 165:16
302:5,8 332:4	37:17 43:17	301:9 386:16	364:18 390:21	169:15,23
332:11	49:9 53:17	tend 155:20	391:2,3	171:6 172:4
tape 125:12	59:9 61:5 66:3	391:7	tests 253:14,16	174:8,10
365:12 380:24	66:10 67:5,9	tension 245:15	thank 19:2 21:6	175:14 176:11
380:24 393:16	67:20 69:17	246:9 252:17	21:13 27:19	176:17 179:18
396:11,12	71:4 79:8,20	253:3 258:1	45:19 51:4	179:18 186:21
tapes 377:6	80:12 82:7,10	262:8 267:14	120:22 123:6	187:19 190:11
378:16 393:16	82:19 86:19,23	288:10,11	123:16 124:20	195:22 197:11
task 229:19	88:14 89:22	tensionfree	125:17 128:16	205:19 206:16
tasks 119:3	92:7,9 93:24	257:17 262:6	150:9 151:18	207:4,11 208:6
tattoo 20:6	106:19,24	365:10,11	171:5 189:11	211:8 212:22
taught 251:23	107:16 109:12	380:23	214:2 215:6,9	215:1 216:18
teach 217:24	114:5 115:2	tenyear 130:3	222:17 273:3	217:15 219:18
218:2,4 250:22	126:9 130:2	294:24 306:15	279:24 308:19	221:3,17 223:5
teaching 218:11	133:18,20	353:17	321:6 338:24	225:24 226:6
271:14 275:13	135:9 136:17	term 37:11	370:3 392:6	226:10 229:18
318:15	145:18 146:9	141:11 142:10	413:11	232:16 233:12
teased 372:5	146:15 148:12	142:13 221:15	thanks 104:13	234:21,22
teasing 321:2	151:2,6,9	243:11 287:9	107:20 219:6	248:11 250:1
technically 17:1	153:2,19	294:23	thats 10:14	259:17 260:21
57:8	154:16 162:24	terms 36:3	13:23 18:2,10	260:21 262:15
technician 25:10	172:10,18	94:21 125:24	20:7 22:20	265:15 266:14
25:17 85:12,19	175:10 177:16	145:8 221:6	23:20 24:21	268:4 270:4
120:12,19	180:8,17 197:4	280:11 293:4	29:17 31:13	274:16 275:24
123:7,14	197:5,12 208:3	347:17 348:24	40:12 44:23	276:12,17
137:16,23	213:20 214:20	367:10 409:7,8	49:3,8 53:19	277:19 285:17
150:12,19	245:13,18	test 189:21,22	54:2,14 56:2	289:19 291:5,7
168:11,18	248:2,19 254:6	189:22 288:4	56:15 67:14	296:19 298:7
194:9,16	256:23 260:6	391:1	69:1,2 71:8	301:10,11
199:10,17	261:13 283:24	tested 190:16	78:11 81:20	302:16 305:2
201:17 244:18	289:16 295:22	240:17	83:3,9 84:5	307:3 309:14
245:1 270:21	312:13 313:6	testified 10:5	90:1,21 95:11	310:8 311:1,4
271:4 274:4,10	313:11 358:12	102:19 159:12	95:15,19 96:10	313:21 316:22
276:15,18,24	370:11,14	327:23 335:4	103:8,9 106:18	316:23 321:5
283:10,16	399:19 406:6	347:8 384:3	109:2 111:6,10	329:6,17 333:9
291:12,19	telling 66:20	testify 20:9	113:9 115:22	341:2 357:9
321:16,23	113:2,5 126:22	testimony 5:4	119:10 121:20	358:10 363:16
368:23 369:6	159:22 160:1	49:1,6,8,11	122:7,24	365:21 370:8
383:6,20 415:4	171:18 193:4	124:12,21	125:20 128:14	377:9 385:8
techniques	193:12 230:2	255:10 369:10	128:23 130:7	390:13,17,24

Marc Toggia, M.D.

Page 464

391:6 392:17	166:24 167:12	105:3,10 109:9	314:4 315:2,12	96:15,18 97:3
392:20 395:8	thin 290:21	111:10 116:5,5	317:1 321:4	97:7,15 98:1,7
395:24 396:18	thing 14:4 15:18	116:21 118:17	339:24 346:1	99:5 100:1
398:4 399:12	96:21 149:22	125:20 129:3	348:10 353:24	102:7,22,23
405:8 406:6	158:9 167:15	131:21 133:1	354:16 358:22	103:2,4 104:3
410:24 411:18	173:10 211:20	133:11,14	361:24 363:21	105:12 108:10
413:8	222:10 244:17	136:7 139:15	367:1 368:21	108:22,24
theirs 249:20	255:5 265:10	140:3 141:19	370:12 371:11	110:17,20
theoretical	282:12 338:15	149:2,21	375:21 378:23	111:4,9,13
113:18 114:15	358:11 375:2	157:16 161:9	381:19,20	112:7 113:8
theories 76:23	386:12	168:7 169:7	388:19 392:23	120:8 121:19
367:20 385:20	things 32:10	172:7 176:5	399:19 408:13	123:4 124:1
therapies	33:1,2 36:22	178:24 181:22	thinking 173:6	125:13 128:21
112:15 376:7	37:12,18 38:1	183:6,6,13	218:18 244:5	128:24 136:10
therapy 79:24	58:3 60:3 62:5	184:13 186:11	thinning 246:6	137:14 138:18
theres 12:11	66:21 67:1	186:14,17,21	thins 245:14	139:5,18,22
17:4 26:19	70:18 71:22	187:11,14,19	third 113:23	141:21 143:18
45:7,9,10 48:1	88:16 94:17,17	189:20,23	thirty 417:16	146:24 147:16
54:22 56:4	117:5,9 129:20	190:7,11	thomas 11:20	148:5,18,21
70:22 82:24	129:21,23	203:16 207:4	218:6	149:5,12,15
84:22 89:11	146:16,23	207:11,19,19	thompson 4:3	150:2,10,23
93:6,9,11	165:12 167:9	207:20,20	5:6 10:9,11	152:21 153:23
103:22 111:7	177:24 198:17	209:4,13,17	14:10 17:24	154:6,10,21
111:19 123:20	202:1,14	213:7 215:1	18:8,15,17,24	155:9 158:12
124:22 130:8	211:14 230:8	219:9,13,23	19:4 21:3,7,13	158:19 159:2,4
134:15 144:24	230:10 236:8	226:6,10,12,15	21:15 22:24	160:5,16
156:5 175:21	244:11 245:9	230:21 234:11	23:6,8 24:18	161:12,14
175:22 180:6	312:18 323:7	234:24 239:1,3	25:1,3,19 26:7	162:22 163:19
195:18 204:15	323:12,21	239:4 241:12	27:6,14 32:3,4	163:24 164:24
206:1,13 223:4	325:7 329:18	241:24 243:6	32:13,17 34:24	166:19 167:4
226:16,17	337:19 353:10	246:16 247:3	36:7 40:11	167:10,23
263:11,13	367:8 389:5	247:16 248:11	41:17 43:7	168:9 169:6
264:13 267:16	390:19 400:22	249:3 250:1,7	44:10,17 45:4	170:20 172:9
268:3 284:4	think 17:1,3	251:3 262:12	45:11 46:1,19	172:17 176:19
353:4 362:14	18:21 19:11	265:14 268:19	46:21 47:3,5	177:21 178:12
362:15 373:20	20:5,7 22:18	273:15 275:18	48:7 49:7 50:1	182:11,18,24
373:22 386:22	23:6 24:11	275:24 279:14	50:15,20 54:9	183:5,8 185:16
theyll 237:13	25:20 27:5	280:14 282:8	55:6 56:17,23	187:8,16
391:15	36:9 39:7,22	282:13 287:22	60:15 61:9,17	190:14 191:17
theyre 54:19	40:10,12 50:6	287:24 288:8	61:24 62:21	192:23 193:9
94:3 121:7	54:24 55:1,19	294:2 295:18	63:23 68:10,14	193:23 194:5
149:17 157:22	55:20 62:10	297:6 302:18	77:3 80:20	194:21 195:11
219:19 298:24	67:7 89:9	303:17,22	85:7,11,23	196:11 197:7
313:17 328:19	91:13,15 92:4	306:8,12,24	87:24 88:7,8	198:15,23
335:17 377:24	93:18,19,22	308:2 309:8,13	90:16 91:19	199:8 200:14
399:5 414:2	94:3,5,7 99:1	309:16,17	92:2,20 95:13	200:24 201:15
theyve 165:6	99:10 104:17	312:3 313:8,21	95:17 96:8,12	201:20 203:15

Marc Toggia, M.D.

Page 465

203:22 204:8	364:1 367:12	tied 265:8	337:17,17	150:24 154:12
204:11,20	367:22 370:7	267:14	338:1,6 363:7	158:20 159:6
205:4,18 208:5	385:24 392:7	ties 43:16,18	368:24 370:12	160:17 228:9
208:9,19 209:6	392:12 394:4	till 283:8	372:6,6 374:23	229:7 245:6
209:19 210:3	395:13,23	time 9:8,15	375:13 378:2	271:8 274:13
212:7 214:23	398:12 399:10	16:14,15 24:6	383:7 385:2	277:5 279:10
215:3 222:2	400:2,13,21	25:11 30:8	402:20 404:10	279:14 281:15
227:6,15,20	401:3,12,17	35:4 38:20	406:12 414:1	282:21 283:19
228:8,15,21	404:24 405:2,9	60:8 65:15,15	415:6	291:22 311:20
229:5,22 231:2	405:19 406:18	70:15 72:12	times 65:3 72:1	318:23 320:21
232:3,16 233:7	407:2,8,23	82:16 83:18,18	98:6 101:1	321:6 322:7
235:6,18,24	408:9 410:14	85:8,13,22	149:11 167:7	372:10 419:8
237:1,15 238:3	411:12,21,23	112:14 116:18	180:19 286:21	toggia1 5:13
239:1,6 242:14	412:9 413:10	120:13,21	286:23 300:8	20:21
243:2,23 245:5	413:20 414:6,7	123:8 137:17	307:7 345:15	toggia10 6:16
245:22 247:19	415:1	138:2 150:13	387:4 408:19	279:9
248:6 249:6	thomson 329:22	150:22 158:1	timing 78:19	toggia11 6:18
252:15 253:24	thought 32:20	165:21 166:4	100:11 103:12	281:14
255:24 257:3	63:2 107:6	166:18 168:12	tired 222:10	toggia12 6:20
257:20 259:9	149:13 163:21	168:20 179:1	tissue 138:20	296:9
260:8,20	178:2 187:9	182:2,6 193:24	184:21 240:10	toggia13 6:22
262:11 263:15	243:15 247:21	194:10 199:11	258:20 269:2	298:16
264:15 266:10	252:1,2 310:24	199:21 200:19	290:7,22 291:1	toggia14 7:5
268:19,23	346:7 384:11	200:21 201:4,8	291:3 359:21	303:5
269:12 270:11	400:15 406:20	202:1 203:11	366:23	toggia15 7:7
270:16,20	410:24	217:17,19	tissues 290:19	314:8
271:7 273:1,4	thousands	218:15 236:7	title 405:20	toggia16 7:10
274:12,21	230:10 363:6	236:11 242:23	titled 103:10	320:1
276:9,14 277:3	three 6:16 38:13	244:19 245:4	today 10:15 21:5	toggia17 7:13
277:14,21	53:10,13 82:21	254:7 270:22	22:8 25:5 27:3	326:14
278:7,15,19,24	98:6 115:21	271:5,19 272:6	27:16 57:22	toggia18 7:14
279:13 281:18	149:11 156:6	276:16 277:1	96:22 124:14	326:19
282:15,20,24	165:3 185:9	279:19 281:6,9	155:8 219:11	toggia19 7:15
283:7,18 285:7	223:10 279:9	286:2 291:13	408:19	380:9
285:24 288:19	293:19 309:14	292:24 295:1	today's 9:14	toggia2 5:16 26:3
290:15 291:9	343:21	297:9,21	toggia 1:21 3:12	toggia20 7:17
291:21 296:14	threemonth	299:22 300:5	5:4,15,17,19	382:21
296:20 298:10	158:1	301:8 305:16	6:6,7,8,17,19	toggia21 7:20
299:21 303:12	threepage 46:3	306:9,15,21	9:22 10:3,10	383:11
304:12 305:24	46:23	308:18 309:2	10:19,21 17:15	toggia3 5:18
306:2 310:15	threw 159:23	312:14 314:22	20:18,24 23:9	27:11
311:7,11,14,19	299:16	314:23 317:6	25:20 26:4	toggia4 5:19
314:14 316:10	throw 294:23	317:21 320:23	85:24 87:18	87:17
318:3,12 319:3	thumb 6:16	320:23 321:3,7	99:21,22	toggia5 6:5 99:20
319:9 320:7	22:23 152:18	321:17 322:2	101:14 103:10	toggia6 6:8
321:4 324:20	278:10 279:1,9	330:4 332:20	104:7 108:16	108:15
325:23 349:12	thursday 89:17	336:4,19	112:22 121:23	toggia7 6:11

Marc Toggia, M.D.

Page 466

228:3	100:10 172:7	travel 300:5,5	140:4 152:5	tumors 407:16
toggia 8 6:13	touched 310:14	302:11,13	169:20 191:4	408:2
238:17	tough 104:15	307:3	219:17 231:8	turkish 282:8,10
toggia 9 6:15	toxicity 240:14	treat 144:2	238:18 244:2	284:2
279:4	track 65:22	322:18 325:11	261:22 310:5	turn 330:19
toggias 97:18	159:13 336:3	325:22 327:9	323:8 325:3	340:8 346:9
told 28:5 29:7	413:13,17,22	344:3,3 345:2	333:1,18 343:9	393:6 402:24
32:11 36:5	tracked 308:7	346:21 359:14	353:11 384:16	tv 264:13
40:8 42:16	tracking 338:5	360:19 361:21	391:18 393:10	tv 6:9,11 18:6
43:19 47:1	tract 128:7,9,11	363:15 366:9	393:13,19	30:24 36:14
88:11 94:17	tradition 375:7	366:18 368:16	394:15,16,17	39:13 53:18
95:23 98:6	traditional	378:12 379:7	395:2 397:10	54:1,8,13 55:3
108:2,4 112:24	112:15 123:22	380:20 396:12	397:13,15,22	55:8 57:4,4,11
114:23 129:4	343:23	treated 112:21	397:24 398:7	57:15 58:7,17
136:22 139:16	traditionally	174:4	398:17,19	62:22 64:13,18
141:20 143:16	389:8	treating 14:11	403:17 404:11	65:2,17,17,19
149:1 156:19	trails 405:13	347:9 369:15	404:12 405:22	67:5,6 72:10
159:16 167:8	train 218:22,24	385:16	406:11,16	72:14,21 73:10
210:9 211:15	288:24 313:14	treatment 36:16	trick 254:20,21	73:11,14,16
233:8,10	trained 58:20,24	39:15 47:11	tried 32:14	74:9 77:5 81:7
244:10 245:8	217:21 306:22	49:19 75:9	372:18 389:11	104:2,6 108:17
251:13 324:17	306:22 312:22	172:2 174:15	trips 309:21	112:8 113:1
345:15 363:21	trainer 313:16	212:4,8,12	trouble 300:16	114:6 115:12
387:22	training 59:5,11	219:22 221:9	true 163:16	116:3 125:19
tolerability	60:9,17 62:10	322:22 334:11	171:15 184:6,6	129:8,11 130:7
359:19	62:11,16 63:5	344:8 345:19	184:8 395:24	131:19 132:16
tolerance	63:10,16,18	347:13 364:22	416:6	133:16 136:18
198:13	64:1 218:23	381:17 382:16	trump 414:20	139:1 144:1,18
tom 81:24 83:4	250:24 272:16	385:10 388:4,4	try 29:13 69:16	144:23 145:5
83:5	273:21 288:24	treatments	160:17,22	145:11 146:18
tomblin 2:20	transcript 97:9	212:20 309:5	299:23 355:6	151:3 152:11
tone 100:11	416:18 417:17	tremendous	trying 29:10	153:7,17,20
top 19:10 69:17	417:19	62:4 78:1	61:12 96:6	154:14 155:2,6
91:7 97:21	transcription	323:10	109:7 110:10	155:13,23
98:19 109:1	419:4	tremendously	115:2 119:5	156:22 158:4
145:18 163:2	transferable	76:18	132:21 141:1	173:7 177:17
174:14 273:2	243:9	trial 9:8 33:16	171:9,10	178:9 179:8,14
277:10 329:4	transient 84:17	77:23 79:6	175:20 199:20	181:7,19 182:8
384:20,20	290:13,20	120:4 121:8,9	200:18,18	182:15,16
395:17,18	transitory 289:7	169:23 170:1	236:1 306:18	183:9,18,19,22
topic 85:5	289:8	174:13 304:21	306:18 313:9	186:8 190:24
topics 70:23	transobturator	306:23 328:6	313:10,13,22	194:20 195:14
total 28:6,6,7	65:7,8,12	345:5 358:22	322:12 329:11	196:5 197:15
74:15 295:20	375:15 380:24	379:4 392:4	345:6 356:7,14	198:8,20 200:1
393:12 411:10	395:21	394:21	357:19 361:24	207:15 208:24
totally 18:14,22	transparent	trials 6:14 36:23	369:13 378:24	210:4 212:10
44:3 96:6	317:12	37:1 47:17	388:1 402:19	215:11,13,14

Marc Toggia, M.D.

Page 467

216:23,24	382:16 385:9	323:21 333:12	267:17 268:5	408:13
228:4 229:21	385:15 387:10	353:12 359:13	underreported	university 337:6
230:18 232:24	387:13 389:19	363:13 370:5	131:5	unpublished
241:9,20	407:16 408:2	374:3 379:19	understand	38:23
242:22,24	tvto 69:24 70:7	381:6,6,11	10:14 15:7	unquote 288:4
243:24 244:3	70:12,14 71:3	382:18 401:1	29:13 42:4	384:20
254:2,14 255:1	73:10	types 19:17	61:10 126:4,24	unrecognized
258:10,24	tvto s 70:3	343:22 368:7	128:1 149:3	224:24
259:11,19,20	tvts 67:21	385:1 394:24	160:24 161:4	unrelated 102:9
260:5 265:21	286:14 305:4	403:16	168:22 182:21	untie 265:12
266:12 267:2	tvts ecur 72:12	typical 77:13	182:23 183:2	unusual 15:5
267:13 271:9	73:10 77:6,9	118:23 173:14	216:8 221:14	59:19
271:22 273:6	77:19 78:9,15	183:11 307:18	227:13 229:2	unwind 265:12
275:20 276:5	78:22 79:4,11	351:11 356:1	232:19 236:1,3	update 280:20
279:21,23,23	80:13,21,24	typically 13:9	236:4 242:2	281:5,9,11
279:24,24	307:19	14:1 37:22	244:15 306:5	404:13
281:19 284:9	tvts ecurs 66:10	38:8 40:22	306:17 313:5	updated 280:23
284:14 285:11	tvttm 55:9 56:11	86:3 130:2	understanding	374:21
285:17,18	57:2 58:5	157:12 224:4	12:2 36:12	upstairs 308:8
290:3 292:11	twelve 19:15	267:7 301:14	57:7 112:19	310:19,21,23
300:17 302:20	234:18	315:5 327:16	144:13 181:24	urethra 124:8
305:4 322:17	twelve hour	348:8 376:11	232:22 265:7	124:11 189:10
322:21 324:9	301:10		266:24 285:16	267:17,19,22
325:9,21 326:5	twenty 294:24	U	understands	268:5,8
327:8 331:13	two 17:20 27:16	uhhuh 88:13	275:23	urethral 115:5
332:15 334:1	57:3 80:4,9	uk 77:17 376:4	understood	118:20 130:21
334:11,20	83:21 86:20	376:12	10:13 15:16	140:17 180:22
336:4,18	93:12 102:9	ultraprotm	24:17 62:9	186:9
337:24 338:7	119:3 165:3	338:18	68:13	urge 315:7
341:5 342:4,8	177:23 228:14	um 394:7	underwent	urgency 404:2,2
344:7 345:1,16	234:16 279:1	unable 29:17	79:13 173:6	urinary 7:15,16
345:19 346:20	280:16 285:14	190:2 349:10	undisturbed	7:21 13:6
347:1 353:8	309:12 336:14	uncommon	254:23	47:12 49:20
359:7,14 360:8	371:15 372:4	314:19	unfortunately	51:19 53:15
360:10,17	375:20 390:7	undergo 143:20	156:10 199:24	128:6,9,11
361:20 362:17	400:21 405:12	396:23	200:5 356:24	212:5,9,20
363:12,23	405:21 406:10	undergoes	unfounded	214:11 322:18
364:20 365:11	409:8	143:13 144:5	42:14	322:23 325:11
366:8,13,15	twopage 44:12	undergone	uniform 79:13	325:22 327:10
368:12,18	tyler 2:22	357:4	unimportant	334:12 335:12
373:13 374:7	type 16:19 42:15	underlined	109:6	344:9 345:2,20
374:18 375:3	55:10 76:3	187:10	unique 114:17	346:22 347:9
375:12,19	125:19 128:10	underlines	114:24 115:3	360:19 361:21
378:5,12 379:6	160:8 179:4	26:16	115:11 124:23	363:15 364:24
379:11 380:19	190:12 238:24	underlying	125:9,21	366:10 368:16
380:24 381:10	240:6 259:15	288:9	251:22 375:3	378:13 380:9
381:16,16	260:5 323:18	underneath	united 1:1	380:11 381:18

Marc Toggia, M.D.

Page 468

382:15 383:13	368:13,19	61:21 63:9	395:18,19,20	vivo 143:21,22
385:17 405:13	377:1,6 378:12	76:7 139:10	395:22	154:15 349:5
405:22	378:16 379:19	210:1 234:6	vessels 114:14	voiding 114:12
urine 390:23	385:16 392:3	243:19 252:11	veterinarian	130:12,17
urodynamics	398:8 404:14	405:15	242:10	180:18 385:3
393:1	409:6,11,23	validated	viability 73:4	volker 7:18
urogynecologic	useful 272:19	398:18	vice 126:16	382:22
266:16	273:6	validates 327:21	vicinity 308:9	volume 55:18
urogynecologi...	usefulness	validation 339:5	video 9:16 25:10	56:3,4 57:9
14:12	374:17	339:9,12,19	25:17,18 85:12	199:24 294:15
urogynecology	uselessness	value 410:11	85:19,20	337:11
12:20 13:18	327:22	vanbuskirk 2:4	120:12,19,20	vtac 74:24
76:17 264:24	user 181:12	variability	123:7,14	
268:13	uses 54:1 89:5	403:15	137:16,23,24	W
urologic 335:14	267:20	variant 224:3	150:12,19,20	wait 119:2
urology 382:5	usual 70:18	variations 33:6	168:11,18,19	209:16
use 6:12 16:16	273:11	345:10	194:9,16,17	waiting 45:19
36:15 39:14	usually 71:10	varied 65:15	199:10,17,18	403:8
42:18 54:13	156:5 293:3	varies 134:6	201:17 244:18	waived 9:5
55:2 58:14,21	301:18 302:15	variety 54:22	245:1,2 270:21	wang 195:19
64:12,15 65:5	302:16 316:22	62:4 64:22	271:4 274:4,10	196:10,19,22
65:23 67:11	326:4 377:24	66:7 88:15	276:15,18,24	354:24 355:4
69:24 86:13	386:14 412:12	94:16 391:1	283:10,16	355:10,15
104:23 106:22	utility 73:3	various 69:14	291:12,19	358:2,4,5
107:17 112:11	322:16 341:5	284:11,21	321:16,23,24	want 14:21
118:7,9,10,11	347:18 367:2	285:10 297:19	368:23 369:6	21:10 23:2
128:20 142:15	374:17	309:20 338:10	383:6,20,21	24:24 35:20,22
144:2 228:5	utilize 71:9	344:5	415:4	51:7 52:3
248:5 249:2,8	utilized 322:15	vary 293:14	videographer	53:12 54:24
249:10,13	utilizing 327:6	vast 19:19	4:16 9:10,13	58:13 59:24
255:2,2 257:10	329:2 366:19	264:20 286:16	200:16	64:5 78:5 81:2
264:16 271:9		404:13	videotape 3:11	90:20 121:1
271:13,18,24	V	venture 132:4	videotaped 1:21	147:10,23
272:11 279:16	vacation 157:20	300:14	5:13 20:21	148:7,8,19,23
280:3,5,16	vagina 114:14	venue 302:3	viewed 313:19	149:8,16,22
281:20 283:20	116:3,4 117:2	verifies 327:21	vince 59:3	152:14,23
286:8 288:4,7	124:3 189:10	versa 126:16	violates 18:21	168:21 178:16
304:24 320:19	264:17	versed 71:21	virginia 1:1 9:21	178:23 180:14
322:17 323:1,2	vaginal 105:20	200:7	visit 165:16	186:20 188:3
325:21 327:9	118:14 119:24	versus 36:17	visits 157:10	196:19 200:22
342:10 344:8	180:21 184:4	78:19 104:22	406:11	208:7,16,22
345:1,18	184:11,24	104:23 188:19	vitae 26:19	209:10,23
346:21 347:8	185:20 203:9	188:22 189:18	vitro 37:19	210:7 213:19
359:14 360:18	265:1 266:21	199:2,2,2	38:22 143:21	213:20 214:2
363:5,14	267:10 343:23	305:4 345:8	205:23 324:5	216:5,6 219:8
364:20 365:3	365:11 380:23	381:6 384:18	347:2 409:23	220:11,16,23
366:9,17	vague 59:16	384:20 394:19	414:22	221:11,17,18

Marc Toggia, M.D.

Page 469

221:20 222:9	192:17	78:1 79:23	215:1 221:23	81:15,24 82:24
224:16 225:17	weakening	86:11 374:2	226:9 227:12	140:22 370:20
228:17,22	291:3	wife 310:20	227:16,22	387:13 390:22
242:5 246:16	webb 1:13	willing 236:21	228:24 229:17	391:5
246:21 247:2	website 308:15	window 309:1	230:21 231:16	womans 136:19
248:9 257:5	week 21:21 28:3	wise 83:19	232:18 234:7	women 7:16,22
262:20 263:22	104:15 280:16	witness 8:5 10:1	235:13,16	13:6 36:17
265:10 269:3	weeks 156:4	14:9 19:2	236:2 237:8	49:24 144:3
269:14,17,22	222:22 223:1,4	24:17 31:24	238:21 242:9	174:2 175:1
270:2 274:22	223:10	35:23 40:9	242:20 243:21	176:7 177:7
277:20 283:23	weight 55:17,21	41:6 43:1,5	245:17 246:24	204:16 205:7
296:18 297:13	56:2,8 57:7	44:7,22 45:9	248:1,24	212:6 241:11
298:12 313:18	76:14 194:24	45:18 49:3,10	252:12,21	256:17,18,20
321:12 338:15	327:16 391:13	50:17 54:6,18	255:19 256:13	276:8 308:16
340:3 371:22	welcome 156:19	56:15,21 59:17	257:8 258:7	322:23 337:5,7
371:22 372:20	228:22 308:22	60:21 61:22	260:4,17	350:15 357:3,4
373:1 376:20	welldescribed	62:24 68:11	261:13 262:22	357:6,6 362:21
394:13 398:10	251:6	76:8 80:17	263:19 265:24	362:24 380:11
wanted 66:1	welldesigned	92:16 95:21	269:6 270:1,14	383:14 393:13
80:8 96:19	270:3	96:1 97:11	270:17 276:11	394:18 396:12
321:9 355:8,13	wellschooled	103:24 104:13	276:17 278:12	405:23
wants 89:7 90:5	358:12	108:9,23 112:3	278:17,21	wont 91:12 99:1
192:3 194:7	went 32:15	113:5 119:14	282:23 285:4	201:24
warning 104:16	150:24 163:13	120:3,22 123:6	285:20 287:18	word 89:5 90:8
105:13,18,24	187:14 310:12	123:16 125:3	290:1 298:6,13	90:10 168:8
106:2 274:15	374:13 394:21	138:1,11	299:13 303:11	169:15 183:14
washington 4:12	403:4	141:19 146:14	304:8 310:2	186:21 249:2,8
wasnt 50:17	west 1:1 9:20	147:14 148:4	311:6,9,13,18	249:10,13
63:1 122:10,11	11:9	149:21 152:17	316:8 317:24	408:18 413:8
127:12 159:10	weve 21:3 27:17	154:24 160:3,7	318:6 319:7,15	words 106:4
175:9 179:12	85:9 165:23	161:9 162:19	324:22 326:1	263:16 384:12
189:18 209:7	201:14 217:10	164:4 165:20	349:14 364:3	work 27:17
214:3 237:23	265:8 352:15	167:14 168:21	367:14,24	28:12 29:23
294:5 305:22	whats 101:12	170:4 176:15	383:2 386:2	59:20,24 110:8
306:10 374:24	141:23 249:18	178:4 182:23	395:15 398:4	166:18 271:21
388:2 410:20	259:10 265:4	183:3 185:4	399:8,18	291:23 295:23
watching 28:22	282:18 329:15	187:11 190:11	400:10,20,23	317:24 318:4,7
water 383:4	356:3 388:8	190:21 193:6	401:10 405:16	318:13 337:4
way 21:11 44:24	391:9	194:3,18 195:7	406:15 407:19	338:11 374:1
69:18 78:20	whatsoever	196:9 197:2,24	408:5 410:10	399:20
84:24 105:23	314:5	199:6,19	411:19 412:5	worked 28:1
206:3 302:3	whisner 2:19	200:17 201:19	413:6,17	63:11 149:24
342:9 349:15	white 258:18	202:23 203:24	414:18 416:5,7	222:17 297:22
413:6	wide 54:22	204:4 205:2,12	417:1	301:9 307:21
ways 69:19	64:22 65:20	207:18 208:13	witnessed	318:1
70:23 390:7	70:22	209:3,12 210:2	289:17	working 60:3
weak 38:5	widely 77:24	212:3 214:20	woman 80:14	84:4 108:3

Marc Toggia, M.D.

Page 470

238:5 239:9	256:20 281:9	58:9 60:18	72:6 119:14	6:11 228:4
249:18 300:6	293:2 295:10	64:19 83:24	143:10 154:8	06 245:4
307:19,20	297:19 359:4	85:4 90:7,9	159:12 163:15	07 7:11 320:2
317:22	374:19 384:3	92:6 94:4 96:3	165:12 171:8	08 6:5 99:20
works 37:10	393:19 395:3	96:5,11 102:11	179:15 181:16	08696131132
150:4	years 19:12	102:16 109:9	202:1,2 204:13	6:13 238:17
world 19:23	28:15 29:6	118:8,12,19	210:22 213:14	09 5:19 6:8 7:6,8
255:23 263:9	62:3 65:16	119:22 124:13	217:13,14	87:17 108:15
264:21 355:19	76:19 82:22	126:5 127:21	219:15 232:6	303:6 314:9
390:4 409:16	83:22 112:18	127:22 138:23	239:9 249:7	095 300:21
412:2 413:2	129:15,16	141:12 142:8	255:6 262:12	
worldwide 46:9	131:11,12	145:8 149:4	275:17 277:7	1
49:18 200:4	140:19 146:7	155:10 161:1	279:21 289:20	1 3:17 8:17 9:16
382:8	151:23 155:1	167:6 168:5	317:9,13,19	25:11 36:22
worthless 195:4	165:4 166:12	171:10,23	363:22 407:1,4	37:3,24 38:18
worthy 407:12	171:20 178:5	175:11 176:6,8	408:18	40:24 55:22,22
wouldnt 64:6	187:23 191:5,6	176:22,23		116:22 130:16
67:9 132:23	200:3 217:8,12	182:13,14	Z	130:17,18,21
210:8,11 214:5	225:9,9 234:16	183:4,14	zero 130:19	134:21 146:21
227:23 242:2	234:16,17,17	185:18 207:13	182:4,6,12	179:24 192:4
255:19 321:1	234:18,19,20	207:19,20,21	183:9 381:9	192:12 195:8
347:10 413:1	243:18 244:1,4	216:20 218:9	0	195:13 197:18
wound 115:7	244:7 256:21	218:11 220:10	00 85:22	206:4,6 207:12
116:13,13	268:14,16	221:10,15,20	000 129:18	208:3 215:22
202:15 289:7	294:19 297:4,6	222:3 223:17	186:7,14,17	261:23 293:16
290:4,12 340:1	306:6 332:14	228:14,22	187:4,13,24	293:23 325:1
340:9 342:19	362:20 385:13	230:16 235:20	189:17 202:3,9	328:15 330:11
343:3 344:4	386:16	236:11,15	204:13 206:22	332:10,23
writing 90:1	yesorno 46:20	238:8 241:18	289:20 293:17	335:4 341:10
320:13 412:7	274:17	248:7,17 249:3	293:23,24,24	342:18 343:11
written 42:18	youd 121:16	254:14 263:10	294:7 295:10	343:13 344:19
wrong 62:15	231:1	263:20 265:9	295:16,17,21	353:11 360:22
129:20 244:5	youll 40:15	270:7 273:13	296:1,1,4,4	366:15 373:12
312:20	41:12 122:17	276:3,3 292:21	298:1,1,2	374:3 377:15
	125:23 126:21	308:22 316:6,8	300:19 301:3	377:20 379:5
X	169:20 182:20	316:18 318:15	366:15	384:9,11
	213:4,4 257:21	319:8,21 333:7	02026591595	392:21 414:19
Y	258:3 399:3,13	336:10 337:6	6:15 279:4	419:3
yeah 85:7	younger 180:11	340:13,20	021 393:13	10 5:6 6:5 29:20
249:17 270:16	youre 10:14	356:7,10,14,21	03617772 7:5	89:17 99:20
278:7 282:3,5	12:7 14:11	370:21 371:8	303:5	239:14 321:17
282:24 312:16	17:24 18:17	372:7 398:24	04 244:19	100 204:16,21
361:23 371:22	29:17 33:13,14	401:2 402:9	05 368:24	205:6 206:12
year 59:10 82:23	34:6 40:3	405:18 406:3	05225354 6:11	256:19 295:10
182:4,7,12	41:21 42:5,5	406:22 408:23	228:3	391:6
183:11,17	43:8 44:8,9	414:23	05225380384	10399348 7:7
214:21 234:15	46:14 57:18	youve 34:3 69:6		314:8

Marc Toggia, M.D.

Page 471

108 6:10	14cv24911 3:4	3:6,7,9 26:9	9:15 129:11	189:17 202:3,9
1098 11:9	14cv24999 3:5	47:8 65:19	271:19 374:21	204:13 206:22
11 150:13	14cv28620 3:6	67:16 70:5	384:5 416:11	261:23,24
234:19 377:4	14cv29624 3:7	85:13,21	21 5:21 87:20	265:14 289:20
110 8:12	15 119:15	129:18 155:3	330:5 383:24	293:17,24
11838868869	187:23 194:10	178:6 261:23	215 4:12	294:7 300:19
7:10 320:1	240:11 273:14	261:24 293:17	2169000 4:5	300:21 301:3
11843352364	295:17 298:2	293:24 294:1	22 8:7	343:5 356:2
6:20 296:9	303:11 386:23	331:10,15,19	228 6:12	357:15 386:18
12 156:8 295:16	16 51:23	377:16 386:11	23 6:5 28:15	389:3
296:1	163 174:1	389:2	29:6 99:20	30 5:14 7:11
12cv02952 1:9	17 8:7,12 129:16	20 5:15 76:19	2327 1:4	20:22 153:3
12cv07924 1:10	140:19 151:23	131:8 200:3	239 6:14	243:18 244:1
12cv09765 1:11	154:24 178:5	217:1 244:4	24 99:14 216:12	268:14,16
12md 1:4	191:6 234:19	296:4 383:7	277:2	283:11 295:21
13 51:10 99:14	256:20 273:1	419:11	24th 27:23 28:2	296:1 298:1
298:11	273:15 322:2	200 215:22	25 5:21 87:20	320:2 387:21
13cv02565 1:12	326:24 330:5	2000 3:15 82:20	361:9,11	417:16
13cv02919 1:13	332:14 385:13	281:24 284:18	26 3:17 5:17	300 65:20 70:5
13cv04517 1:14	17year 130:20	2001 82:20	9:16 346:9	303 7:6
13cv04730 1:15	182:1 332:20	137:5	361:9	314 7:9
13cv07283 1:16	18 326:24	2002 70:10	266 351:16	32 120:13
13cv10150 1:17	328:23	217:20 292:17	352:2	320 7:12
13cv11022 1:18	18th 3:15	2005 70:10	27 5:18 6:8	322 5:6
13cv14355 1:19	19 5:19 87:17	83:20	108:15 270:22	326 7:13
13cv14718 2:3	99:15,15	2006 295:8,13	279 6:15,17	327 7:14
13cv14799 2:4	199:11 340:8	295:14,24	28 4:4 7:6 109:4	33 29:21
13cv16183 2:5	340:15 393:24	297:17	303:6	3377 1:23
13cv16564 2:6	19034 4:12	2008 105:16	281 6:19	34 5:15 20:24
13cv17012 2:7	19103 3:16	300:20	289 393:7	3404 11:11
13cv18479 2:8	1998 271:19	2009 83:20	29 7:8 314:9	370 1:23
13cv22606 2:9	292:11	88:19,20	29464 4:5	38 25:11 150:22
13cv24393 2:10	1999 58:18 59:6	107:23 108:5	296 6:21	380 7:16 284:9
13cv29260 2:11	59:9 82:20	109:3,21	298 6:22	383 7:19,22
13cv29918 2:12	112:9 129:4	300:19	2nd 9:15	3883 289:4
13cv31818 2:13	292:11	2010 298:2		39 291:13
13cv31881 2:14	19th 89:17	2011 107:24	3	393 5:6
13cv32627 2:15		298:1 392:15	3 5:19,21 11:11	
14cv09195 2:16	2	393:24 396:16	27:18 85:22	4
14cv09517 2:17	2 1:4,9,10,11,12	398:24	87:17,20	4 5:21 6:8 7:8
14cv10640 2:18	1:13,14,15,16	2012 121:5	117:18 120:13	8:12 47:9
14cv12756 2:19	1:17,18,19,21	214:23 215:8	120:21 121:14	87:20 88:2,7
14cv13023 2:20	2:3,4,5,6,7,8,9	2013 297:3,14	123:8,21 130:8	108:15 117:18
14cv14664 2:21	2:10,11,12,13	297:17 298:2	131:17 137:17	150:13,22
14cv16061 2:22	2:14,15,16,17	378:3	150:21 186:7	168:12,20
14cv19110 2:23	2:18,19,20,21	2014 328:16	186:14,17	245:3 266:7
14cv22079 3:3	2:22,23 3:3,4,5	2015 1:21 3:9	187:4,13,24	314:9 357:16

Marc Toggia, M.D.

Page 472

369:21	6 108:21 244:19			
40 146:7 271:6	245:4 261:20			
362:20 386:23	266:7 270:22			
400 4:11 308:9	271:6 274:5			
310:24	276:19 296:4			
41 85:13 120:21	298:1			
415 419:3	60 66:11 293:13			
43 29:21 274:5	61 393:13			
44 123:8				
46 89:17	7			
47 276:19	7 8:17 261:20			
49 378:19	277:2 281:20			
	282:11,14,17			
	282:23 283:1			
5	283:11 291:13			
5 7:6,11 37:21	393:13			
37:21 38:21	700 357:4			
65:14 109:4	71 402:7 403:1			
120:5 123:21	403:11			
191:14 192:13				
192:16 194:10	8			
195:2,9 199:11	8 8:13 283:2			
205:23 234:19	321:17 322:2			
293:23,24	332:10			
303:6 320:2	800 215:22			
322:1 324:7	80s 382:6			
387:9 389:12	843 4:5			
416:11	86 244:5			
50 28:6,7,9,11	87 5:22			
28:16 29:8,14	877 1:23			
146:7 234:12				
235:1 268:14	9			
362:20 415:6	9 187:17 368:24			
415:10	381:7 383:7			
500 4:11 65:19	415:6,10			
67:16 155:3	90 157:1,2,4			
178:6 293:16	161:19 163:12			
293:17,23,24	216:16 332:21			
294:1 337:14	900 393:3			
51 168:12	917 1:23			
5131885 4:12	95 65:2,13			
53 8:12,13	300:21 382:1			
54 168:20	96 244:4 292:13			
5672 1:23	292:14			
58 137:17	97 292:14			
591 1:23	99 6:7 382:1			
6				